S. HRG. 107–631

PRESCRIPTION DRUG ISSUES IN THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

JULY 24, 2001

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PRESCRIPTION DRUG ISSUES IN THE DEPARTMENT OF VETERANS AFFAIRS

TUESDAY, JULY 24, 2001

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The committee met, pursuant to notice, at 2:35 p.m., in room SR–418, Russell Senate Office Building, Hon. John D. Rockefeller IV (chairman of the committee) presiding.

Present: Senators Rockefeller, Wellstone, Miller, Nelson, Specter, Campbell, and Craig.

Chairman ROCKEFELLER. I will make an opening statement and others are welcome to do that. The hearing will be called.

I have spent most of my last several weeks to order negotiating prescription drug benefits for the non-VA population, and it is an unbelievably complicated, contentious, and sometimes rather ideological, sometimes theological subject. But some things are very clear, and let it be said here, Medicare beneficiaries need a prescription drug benefit. We have to come through one way or another.

We have to come through, and we have to come through with a decent drug benefit, not just a drug benefit—but a decent drug benefit, which is all made the harder because of the tax cut bill which we have passed which has constrained what we can spend to an amount which may, in fact, not equate to a decent drug benefit—all of which we have to factor in as we look at it in the non-VA sector.

The reason that the Medicare beneficiaries need it is because they are forced to choose between drugs and other human needs, which we hear about a lot. But there is another reason that we have to make sure that Medicare beneficiaries get prescription drugs and that is the reason which brings us here this afternoon—they need it because their lack of an affordable prescription drug benefit is, in fact, cutting into the services provided for our Nation's veterans. So the two are inextricably linked. What we don't do for one hurts the other, in this case, the veterans, hence this hearing.

I don't think it will come as a surprise to the people in this room that there is substantial cost shifting going on here. While a drug benefit remains out of reach for many in Medicare, veterans over 65 years of age are turning now in extraordinarily increasing numbers to the VA for low-cost prescription drugs. These are the low-cost prescription drugs which some of us helped negotiate back in 1992 and it became a model of how you leverage volume for low

cost. So as a result, the VA is incurring increasingly high expenditures.

Others who raise concerns about the high cost of a Medicare drug benefit don't seem to understand that the government is already paying for the drugs of older patients in many cases. Veterans with other health care options are, in fact, coming in droves to the VA, many of them for the sole purpose of getting inexpensive prescription drugs. I do not blame them for that, but that is something that needs to be talked about.

They tell VA doctors that they are not coming for VA care and they tell me that they are not coming for VA care. They are coming for low-cost prescription drugs. But, obviously, before a drug can be prescribed, a patient has to be examined, and, therefore, the VA physician has that responsibility and then only at that point can prescribe a drug. As a result, we sometimes end up with a duplication of health care services.

So this cost shifting, together with an expensive tax cut, which I have already mentioned, has handcuffed us powerfully—powerfully—and that means that the VA health care system is being and will be shortchanged. I have said that at earlier hearings. A byproduct of that could mean that enrollment for higher income veterans might be put at risk. I don't know if that is the case. I, and I think all members of this committee, don't want to see these veterans pushed out of the Department of Veterans Affairs. But at some point, we have got to deal with these problems.

I will do everything in my power to make sure that VA has the resources to care for all veterans, regardless. We changed the eligibility status. When we change the eligibility status, we change the habits, the expectations of veterans of whatever age and income to be able to ask for service. But we must be concerned and note that there are very major problems.

The veterans' health care system is under a financial attack. VA expenditures on prescription drugs have increased dramatically, as I have indicated.

So now we are going to hear more about this this afternoon, because this is what our hearing is about, as well as what works and what doesn't work and what we might do in the area of cost containment, for example, for prescription drugs. We also have a proposal from the VA to increase the prescription drug copayment from $2, which folks are accustomed to paying, to $7. If you do the math, on certain kinds of incomes, that can become a burden, a very heavy burden in the State that I represent, in any event, and we need to learn more about that and the need for that and the thinking behind that. So these are serious issues that have spillover effects into other aspects of our health care systems. They will directly affect who gets to enroll for VA health care.

[The prepared statement of Senator Rockefeller follows:]

PREPARED STATEMENT OF HON. JOHN D. ROCKEFELLER IV, U.S. SENATOR FROM WEST VIRGINIA

Good afternoon. I've said it before in other forums, and I will say it here: Medicare beneficiaries need a prescription drug benefit. They need it because too many seniors are forced to choose between prescription drugs and other basic needs. But there is another reason Medicare beneficiaries need a drug benefit—a reason which

brings us here today—they need it because their lack of affordable prescription drugs is cutting into services provided to our Nation's veterans.

I don't think it will come as a surprise to the people in this room that there is substantial cost shifting going on here. While a drug benefit remains out of reach for many in Medicare, veterans over 65 years of age are turning to VA for low-cost prescription drugs in significant numbers. As a result, VA is incurring increasingly high expenditures. Others who raise concerns about the high cost of a Medicare drug benefit don't seem to understand that the government is already paying for drugs for older patients in many cases.

Veterans with other health care options are coming in droves to VA—many of them for the sole purpose of getting inexpensive prescription drugs. They tell the VA doctors that they are not coming for VA care, and they have told me that. However, because VA rightly must examine each patient before dispensing medications, we end up with a duplication of health care services.

This cost shifting, together with an expensive tax cut that has handcuffed us financially, means the VA health care system will be short changed. A byproduct of that could mean that enrollment for higher income veterans might be put at risk. I, and I think all members of this Committee, don't want to see these veterans pushed out of VA.

I will do everything in my power to make sure that VA has the resources to care for all veterans who choose to come to VA. But we must be concerned and note that there are major problems. The veterans health care system is under financial attack. VA expenditures on prescription drugs have increased dramatically.

We will hear more about that this afternoon, as well as what works and what doesn't work in the area of cost containment for prescription drugs. We also have a proposal from VA to increase the prescription drug copayment—from $2 to $7—and we need to learn more about that. These are serious issues with spillover to other health care systems. And they will directly affect who gets to enroll for VA health care.

I'm very pleased to welcome our witnesses today, especially our distinguished VA Secretary, Anthony Principi, and the VA Inspector General, Richard Griffin. Your presence here today signals the seriousness of these issues. I look forward to hearing from you both. And I also appreciate the appearance of Dr. Garthwaite and Michael Slachta.

Chairman ROCKEFELLER. I am very pleased to welcome our witnesses today, especially our distinguished Secretary, Anthony Principi, and the VA Inspector General, Richard Griffin, and others I will introduce at the proper time.

Having ended my statement, I would like to, in order, call upon Senator Campbell, Senator Miller, Senator Wellstone, and Senator Nelson.

Senator CAMPBELL. Mr. Chairman, I think I will just introduce my comments for the record. I have some questions to ask a little later, but do want to welcome Secretary Principi and the panel to be with us today.

Chairman ROCKEFELLER. Thank you, Senator.

[The prepared statement of Senator Campbell follows:]

PREPARED STATEMENT OF HON. BEN NIGHTHORSE CAMPBELL, U.S. SENATOR FROM COLORADO

Thank you, Mr. Chairman. Thanks for holding today's hearing to discuss VA pharmaceutical issues that will affect prescription drug coverage for our veterans' community. And, I want to thank my friend Secretary Principi and his colleagues and the others who have come today to testify on these issues. I recognize the efforts the Secretary and the VA have made thus far in responding to the concerns of veterans.

As I mentioned at last week's hearing on homeless veterans, I am concerned about the tight fiscal constraints faced by the VA in 2002. Even though most of the increase in discretionary funding will probably go to health care, I can only begin to guess how it will affect the overall quality of benefits and care received by our veterans. The current funding simply cannot provide for the level and quality of care that is needed in certain specialized programs like spinal cord injury.

Mr. Chairman, I look forward to today's testimony regarding prescription drug coverage in the VA. The cost of prescription drugs has contributed to massive increases in the cost of health care in this country. And, now, with the aging of our population, there will be a corresponding increase in the need for multiple prescriptions. Even though the Veterans Health Care Act of 1992 limits the prices that drug manufacturers can charge the VA, those same dynamics will affect our veterans' population.

I want to commend the VA for its broad efforts to serve more veterans with limited resources. While the restructuring of the VA health care system that has taken place in the last few years has been an enormous task, it has seemed to make improvements in many regions throughout the country. I still think it is shameful that vets have to go to Mexico to buy medicine because they can't afford to buy at American pharmacies.

I look forward to working with the VA and with members of the committee as we look at ways to ensure each deserving veteran access to quality, affordable health care.

Thank you, Mr. Chairman.

Chairman ROCKEFELLER. Senator Miller?

Senator MILLER. Thank you, Mr. Chairman. I just want to say, and I will have a question or two when we get to that part, but I just want to say how much we all appreciate the efforts that you and your staff continue to make on behalf of our Nation's veterans. I especially want to thank you for this prescription drug issue. That is an example of how you go about doing business.

The increasing demand for prescription drugs by our veterans, we know must be appropriately addressed. I believe that you are committed to finding the best solution from a quality of service standpoint first and a value for the dollar standpoint second and I encourage you to continue to evaluate, improve the methods to find a way to dispense prescription drugs to our veterans and make sure that they receive the first class care and service that they deserve. Thank you, Mr. Chairman.

Chairman ROCKEFELLER. Senator Nelson, would you yield for a moment to Senator Specter, who has just come?

Senator NELSON. Yes.

Chairman ROCKEFELLER. I would appreciate it very much.

Senator SPECTER. Thank you very much, Mr. Chairman. Thank you for convening this hearing. The issue of prescription drugs is one of overwhelming importance. Having Secretary Principi here today and his distinguished supporting cast doubtless will shed special insights into this very serious problem and probably tell us how to solve it for seniors generally. So I am looking forward to the testimony on a matter of enormous importance.

We all know how expensive the drugs are and we do know that our veteran population consists largely of men and women who have problems, many of them connected to the service that they worked for, some not provably so. Those expenses are overwhelming and it is a matter of highest priority that the Veterans Administration find an answer to provide the appropriate help and, as I say, perhaps insights into the problem for the community at large. Thank you, Mr. Chairman.

Chairman ROCKEFELLER. Thank you, Senator Specter.

Senator Nelson?

Senator NELSON. Thank you, Mr. Chairman. I, too, would like to thank the Secretary and your distinguished team for appearing before us today as we look at the phenomenon of new medicines that are available today that not only increase the likelihood of one's

good health and longevity, but also are now in the process of accomplishing what previously could only be accomplished through surgery, that we are now doing so with less pain and sometimes at a lower cost. Sometimes the pain is more in the cost than it is in the condition.

This was an outstanding accomplishment that Congress succeeded in extending the prescription drug coverage to all military retirees. Unfortunately, as we all know, those who have only Medicare still lack the kind of coverage that we are very fortunately extending to our military retirees. These beneficiaries are now having the opportunity to obtain their coverage for prescriptions through VA pharmacies and through the system. We must, of course, pay close attention to the cost not only to the government but the cost to the military retiree.

Later in the question period, I am going to raise a question about the copay and the amount that it was raised and the logic behind raising it from $2 to $7, but before I get to that, let me congratulate your folks for working very diligently to make sure that we are providing the right kind of prescription drug benefits to our retirees. I will question a little later how this is being accomplished in every instance.

So thank you. I look forward to your answers and getting a better understanding of the issues that need to be addressed, not only with veterans but also it may be helpful to us as we look toward how to solve the problem of those who are uninsured through Medicare at the present time. Thank you.

Chairman ROCKEFELLER. Thank you, Senator Nelson.

Senator Wellstone?

Senator WELLSTONE. Thank you, Mr. Chairman. I know we want to get to the Secretary. Welcome, Mr. Secretary, and I will do this in 1 minute.

I am also interested, Mr. Secretary and others, in exactly why $2 and $7 on copay. I also want to just associate myself with the comments of the chair to say, as we think about moving forward with this prescription drug benefit, there are two kind of facts that just kind of stare you in the face.

One of them is that the VA health care system is under additional strain because there are people who are Medicare recipients who don't get the benefit and then come to the VA system. If we did a better job of really providing this benefit to people, I think that would take some of the strain or stress off of the VA health care system.

And then the other point, Mr. Chairman, which I think is, frankly, very relevant to this discussion about how we are going to do it is we have a working model here in the VA system which says you can have cost containment and you can provide a good benefit to people. I think we ought to be serious about what kind of cost containment measures we are going to take as we hopefully extend this on to Medicare. VA, as far as I am concerned, presents one very compelling model about how we might do it, and I am done.

Chairman ROCKEFELLER. Thank you, Senator Wellstone.

With that, I might also recognize—actually, Mr. Secretary, you appear to be both the IG and the Secretary at the same time because you have both cards directly in front of you——

[Laughter.]

Chairman ROCKEFELLER. So I want to separately introduce Richard Griffin——

Mr. PRINCIPI. We wouldn't want that.

Chairman ROCKEFELLER [continuing]. And Michael Slachta, Tom Garthwaite, and John Ogden. Mr. Secretary, please.

STATEMENT OF HON. ANTHONY J. PRINCIPI, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY THOMAS L. GARTHWAITE, M.D., UNDER SECRETARY FOR HEALTH, AND JOHN E. OGDEN, CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT STRATEGIC HEALTH GROUP

Mr. PRINCIPI. Thank you, Mr. Chairman, members of the committee. It is always a pleasure—most of the time—to be with you——

[Laughter.]

Mr. PRINCIPI. This is an important hearing and I applaud you for holding this hearing on a very, very significant issue for VA and all of American health care. I agree with my friend from Minnesota that the VA could be a model for the private sector. I think we have learned a lot of important lessons.

But the challenge is significant. In 1990, the pharmaceutical bill, just for products only, was $750 million. That is not the cost of administration, just $750 million to pay the tab to the companies for products that we purchased. Today, it is $2.5 billion and growing. In 1990, it was 6 percent of our budget. Today, it is 12.5 percent of our budget, our medical care appropriation. So it is having a very, very significant impact on our system.

I am proud that VA has taken some very, very significant steps over this period of time to improve our procurement, our management, and our storage of pharmaceuticals. I think these significant accomplishments would not have come about were it not for the leadership of our pharmacary service, John Ogden and his team under the leadership of Dr. Garthwaite. I think it is the best in this Nation. I think great strides have been made since the 1980's, through the 1990's, to control the cost of pharmaceuticals. Were these steps not taken, I am absolutely convinced we would have had to expend an additional half-billion dollars or more were it not for these efforts.

In the 1980's, we witnessed a significant increase in prescription workload and the expenditure for pharmaceuticals. The demand for the drugs was absolutely infinite as new drugs came online along with new treatment modalities at the time of finite budgets. The traditional ways and culture in the procurement and storage of VA pharmaceuticals needed to change.

1988, I think, was the first significant step, and I remember it well. It was intravenous [IV] solutions and it was our first national contract for IV solutions. I recall some people saying it can't be done, it shouldn't be done, that doctors will leave the system. However, there was buy-in by the physicians and everyone else. As a result of that one national contract, in the first 3 years, VA saved $100 million that went to expand the reach of health care. Over the same period of time, from 1991 to the present time, we have saved significant money with that.

The second important step that took place——

Chairman ROCKEFELLER. Mr. Secretary, what did they say to be negative about IV's? What did they say? I am fascinated by that.

Mr. PRINCIPI. Well, they just said that you needed to have four or five different manufacturers producing the IV solutions, that people were accustomed to using a certain type of IV solution, the way the product was packaged. Incredible arguments were being proposed to stop this national contract.

But VA persisted and said this was the right thing to do. It would save us money. And the result was, it saved extraordinary amounts of money just for this one product alone. I think that began the process of looking at standardization and volume purchasing and committed use contracting. I think that has resulted in the $540 million or thereabouts that has been saved.

I think the next important step that was taken back then was linking our VHA with our acquisition service. For all too long, there were big barriers between the people who procured the pharmaceuticals and the people in VHA who treated the patients. Well, those barriers came down and the treating physicians were part of establishing the national formulary and what kind of drugs we should be buying. I think linking the two has been an important milestone in the model that we have established.

Then you may remember, in 1990—I remember it well—a linkage was established between VA and Medicare pricing and VA pricing went up. But what happened shortly thereafter, in 1991, working with this committee in 1992, we delinked them in the legislation dealing with pharmaceutical pricing. As a result, VA pricing came down and we have been the beneficiaries of the work of this committee.

So our business strategy, not clinical strategy but business strategy for managing pharmaceutical benefits within the VA is a simple one. Physician buy-in, leveraged national contracts are used whenever clinically possible in contracting for high-volume, high-cost pharmaceuticals.

I mentioned that our utilization and expenditures has increased. In 1990, we were writing 56 million 30-day equivalent prescriptions. In 2001, we are up to 160 million 30-day equivalent prescriptions. So you can see the dramatic increase in the number of people who have come to us seeking the pharmaceutical benefit and also the care associated with that.

The reasons for the increased utilization? 700,000 additional veterans have come to us in the past 5 years. VA's shift from inpatient care to outpatient care, along with more aggressive therapy for common diseases among the VA population, medical inflation, and the introduction of new, more effective drug products, as well as brand products tending to be of higher cost than the generic products have all led to increased utilization.

Deterrent to the question you raised, Mr. Chairman, about the lack of a Medicare benefit on VA expenditures, the short answer is, yes, it has had an impact. Veterans who have dual eligibility or even triple eligibility—are Medicare eligible, VA eligible, and DoD eligible, will seek the best pharmacy package available, and VA clearly has the best program for pharmaceuticals. We have a low

copayment. We don't have any enrollment fee. Therefore, I think veterans just tend to come to us.

Now, if there was a Medicare pharmaceutical benefit, I think we would have to see what the nature of that benefit was as to whether it would depress demand in the VA. But again, ours is a very generous benefit, the way it should be, and the question of how much it will depress demand I really believe will depend directly on the nature of the benefit that the President and the Congress should agree to at some point.

But we clearly are the recipients, if you will, of that workload because they have nowhere else to go. They simply have nowhere else to go.

Let me talk about the copayments. We have proposed an increase in the copayment from $2 to $7 as Congress gave us the authority in the millennium health care legislation. The copayment hasn't been raised since 1990, when it was established at $2, and during the same period of time, as I have indicated, our pharmaceutical bill has grown over 200 percent. Those dollars stay with VA. They don't go into the general treasury. So the increased collections will allow us to buy more pharmaceuticals for our Nation's veterans.

I will add, however, that I have always believed that an increase in the copayment for pharmaceuticals should be looked at in conjunction with other copayments that we have. The copayment for outpatient care—I believe a $50 copayment for basic outpatient care is too high and that should be reduced. I am very hesitant to move forward with a copayment for pharmaceuticals that doesn't look at the other copayments that we charge our Nation's veterans to ensure that they are all reasonable and consistent and that they can afford the care that we provide.

So, yes, I do believe it is warranted. The cost alone of administering our pharmaceutical benefit is about $7.28. Now, I have to question why that is so high. I think we need to bring down our administrative costs. But that doesn't take into account the $14.50. The average cost of every prescription we write is about $14.50, when you look at 160 million 30-day prescriptions and a $2.5 billion budget for pharmaceuticals. So we are paying $7.28 to administer this program, mail out the pharmaceuticals to veterans, and then the $2.5 billion to buy the drugs. So it is very, very costly.

But I do believe the Department needs to look carefully at this outpatient visit, $50 to have your blood pressure checked or whatever, a basic exam. I think it should be tiered. I think preventive health care should be zero, a basic exam around $15 or $20, in that range, and around $50 for a more complex visit that requires perhaps some testing. So I just wanted you to know, I am looking at both. I am not trying to say they should be linked, but I am very hesitant to go forward after the comment period with one without looking at the other.

Just a quick word on DoD procurement. I think we have made great strides between VA and DoD in joint contracting. I have always believed that these two procurement systems should be consolidated, but not the clinical side of the house. Each should maintain their own formularies. But clearly, with respect to the procurement and the distribution of pharmaceuticals, medical/surgical equipment, and supplies, I believe all of us—veterans, military, and

taxpayers—would be better served if we brought the sheer purchasing power of both of those systems under one roof, working jointly, in a joint type of command system. I think very, very significant savings could accrue, saving dollars that are needed to expand the reach of health care.

With that, I will close, Mr. Chairman, and I will be more than happy to try to answer any questions you might have.

[The prepared statement of Mr. Principi follows:]

PREPARED STATEMENT OF HON. ANTHONY J. PRINCIPI, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairman and Members of the Committee:

I am pleased to have this opportunity to address the significant accomplishments that the Department of Veterans Affairs (VA) has made since 1988 towards effective and efficient management of pharmaceuticals.

BACKGROUND

In the 1980's, VA officials recognized the need to direct significant attention to the cost and utilization of pharmaceuticals within the system. In that decade, several forces converged on VA and led us to build an infrastructure that allows VA to successfully manage pharmaceutical procurement and delivery. First, the 1980's witnessed a steadily increasing prescription workload and expenditures for pharmaceuticals. Second, the demand for drugs was infinite in an era of finite resources. Third, the tradition and culture in the procurement and storage of pharmaceuticals within VA was no longer contemporary.

VA's pharmacy benefits management initiatives have resulted in significant enhancements in the quality, consistency, and cost effectiveness of pharmacy services provided to our patients. The attached chronology describes significant milestones since 1988.

VETERANS HEALTH ADMINISTRATION'S (VHA) PHARMACY BENEFITS MANAGEMENT (PBM)

The mission of VHA's PBM is to enhance the appropriate use of pharmaceuticals in the veteran population. The five major core functions of the PBM are (1) drug use management, (2) managing the distribution of drugs and related services, (3) managing the costs of pharmaceuticals, (4) outcomes research, and (5) education.

The PBM facilitates VHA's National Formulary (VANF) Process through the use of a Medical Advisory Panel (MAP) and a committee representing each of the 22 Veterans Integrated Service Network (VISN) Formulary Committees. The MAP is composed of field-based practicing VA physicians, one Department of Defense physician, and a senior physician from VHA's Office of Quality and Performance. These two groups are the primary decision-makers concerning the drugs listed on the VANF and are also responsible for identifying and fostering the development of pharmacologic treatment guidelines that reflect best practices associated with treating a particular disease state and the dissemination of that information.

The business strategy for managing pharmacy benefits within VA is a simple one. Leveraged national contracts are used whenever clinically possible in contracting for high-volume, high-cost pharmaceuticals. The process is clinically driven with a goal of standardization of product. The process is grass-roots in nature, is driven from the clinicians in the field, employs evidenced-based drug class reviews (including data in the VA population where it exists), and involves evaluating products and groups of products based on efficacy, outcomes, safety, compliance, VA patient needs, and pharmacy factors. VA has been very successful in these types of contracts and other similar contracting strategies. From 1996 through February 2001, VA officials estimate $540 million in accumulated cost-avoidance from such contracts. As explained elsewhere in this statement, the average unit cost of outpatient prescriptions is not the key driver of increased expenditures. VA drug cost and utilization data show that the average cost per 30-day equivalent prescription in July 1999 was $12.68, increasing to only $13.48 in January 2001. An increased number of patients treated and the increased utilization of pharmaceuticals are the primary drivers of increased expenditures.

Utilization & Expenditures:

Outpatient prescription workload increased from 56 million prescriptions in FY 1990 to an estimated 100 million prescriptions in FY 2001. While the 56 million figure for FY 1990 is predominantly 30-day quantities, the 100 million figure for FY

2001 represents multi-month prescriptions, which actually equate to approximately 160 million 30-day prescriptions. Thus, over 11 years, the number of 30-day equivalent prescriptions has increased by almost 200 percent.

Expenditures for pharmaceuticals for both outpatients and inpatients have increased from $715 million in FY 1990 to an estimated $2.5 billion in FY 2001. As a percent of VA's medical care appropriation, pharmaceuticals expenditures averaged 6 percent from FY 1980 through FY 1995. Beginning in 1996, the percent has increased each year and will represent approximately 12.5 percent of the medical care appropriation in FY 2001. These percentages are less than those seen in health care organizations in the private sector even though the pharmacy benefit in VA is generally broader in scope than is the pharmacy benefit in most private sector plans.

The reasons for the increased utilization of pharmaceuticals in VA include an increased number of patients served by VA (700,000 more patients in FY 2000 than in the four prior years); a shift from treating patients in the acute care setting of the hospital to ambulatory care with a focus on disease prevention and amelioration; more aggressive therapy for common diseases among the VA population (e.g., hyperlipidemia and diabetes); medical inflation; and the introduction of new and more effective drug products. More patients treated and the introduction of new drug products stand considerably above the other drivers as reasons for increased pharmaceutical utilization and expenditures.

One example of the impact of a new therapy on VA expenditures is the drug imatinib (Gleevec®). Imatinib is used in the treatment of Chronic Myeloid Leukemia (CML), which can occur at any age, but which more commonly affects middle-aged and older individuals. We have determined that there are currently 160 patients with this diagnosis enrolled in the VA healthcare system who potentially could be prescribed this medication. The estimated annual cost of treatment for patients receiving this therapy is between $20,000 and $30,000. Due to the high cost of the annual therapy, we plan to track the number of new patients who are being treated with this drug. In the absence of a Medicare drug benefit, eligible veterans over age 65 with a diagnosis of CML who have never accessed VA for medical care could be highly motivated to enroll in the VA health care system solely as a means to gain affordable access to imatinib.

Lack of Medicare Benefit and Impact on VA Expenditures:

While it is difficult to quantify the impact on increased utilization and related expenditures for pharmaceuticals due to the lack of a Medicare drug benefit, VA staff report anecdotal cases where dual eligible veterans have chosen to access VA for the drug benefit that is a part of our overall health care system. A portion of these veterans indicate a desire to have VA serve as a pharmacy only. We do not believe that VA should only provide pharmacy services, nor do we believe Congress, in enacting provisions of title 38, contemplated that VA act only as a pharmacy. We believe that when such veterans become aware of the positive patient outcomes associated with VA's continuum of care delivery model and the safety and health risks inherent in a fragmented pharmacy-only benefit, they will want their care coordinated and managed by VA health providers. From a financial and clinical perspective, the important lesson learned from VA's experiences concerning pharmaceuticals is that effectiveness and efficiency can be achieved when the providers who treat patients are actively involved in formulary decisions; best clinical practices are employed; and volume-based and committed-use contracting are used when clinically feasible.

VA/DoD Joint Pharmaceutical Activities:

As of July 2001, VA and DoD have 46 Joint National Contracts, three Joint Blanket Purchase Agreements, 23 pending, and 29 proposed joint contracts. Additionally, VA currently has 52 unilateral contracts and DOD has six. Some of these contracts are for high volume/high dollar items and will be considered for joint contracting as they expire. VA and DOD have built the necessary clinical and logistic infrastructure to support ongoing joint contracting activities that will benefit taxpayers and most importantly, our nations veterans, active duty and dependent personnel. VA is committed to the goal of leveraging VA and DoD purchasing power whenever clinically feasible.

Pharmaceutical Copayment:

The proposed increase to the medication co-payment was initiated after passage of Public Law 106–117, The Veterans Millennium Health Care Act. This law gave the Secretary of the Department of Veterans Affairs the authority to increase the medication co-payment amount. VA has proposed to increase the co-payment amount from $2.00 to $7.00 per 30-day prescription supply with an annual cap of $840.00 for priority 2 through 6 veterans. The proposed regulation was published

in the Federal Register on July 16, 200, for the initial 60-day public comment period. We believe that the proposed medication co-payment is reasonable when compared to most medication co-payments levied in the private health care industry.

CONCLUSION

Mr. Chairman, VA has many lessons to share in the area of drug contracting, drug utilization management, drug distribution and achieving positive outcomes from drug therapy. While significant milestones have been reached in achieving cost avoidance through contracting activities within VA and jointly with DOD, even greater cost avoidance has been achieved by identifying and encouraging best practices, developing and promulgating drug treatment guidelines and through recognizing the value of pharmaceuticals in the treatment of disease. It is gratifying to know that our cost avoidance efforts have been accomplished while improving the consistency of drug therapy across the VA health care system. As a result of our clinically driven, cost avoidance efforts, VA has been able to partially offset the cost of providing care to the large number of veterans enrolled in the VA health care system.

In closing, one example illustrates our efforts to date. Specifically, the use of atypical anti-psychotics in treating mental health conditions has resulted in significant utilization and expenditures for these products. However, a significant number of veterans receiving treatment with these products lead productive lives, contribute to society by holding jobs, and experience fewer visits and hospital stays due to their underlying condition. The number of VA patients treated with atypical anti-psychotics has doubled from 35,000 in October 1998 to approximately 70,000 in March 2001. The number of prescriptions dispensed for atypical anti-psychotics has increased from 700,000 in FY 1999 to a level of 1.1 million annually in FY 2001.

I am also pleased to report that VA mental health professionals are contributing to providing quality medical care at an affordable price in those instances where no medical consensus or evidence exists that one product has more clinical value than another. While prescribing decisions are made by VA psychiatrists based on individual patients' clinical needs, history of medication response and potential vulnerability to side effects, they do so with an eye towards cost-effective therapy. VA's psychiatrists clearly recognize not only their commitment to patients and patient care, but also to their ethical mandate to recommend/prescribe the most cost-effective treatments, considering that some patients will respond to relatively less costly drugs, while others will require more costly drugs. Reliance on less costly drugs whenever practical frees up scarce resources, which can then be used when more costly therapy is necessary.

I recently shared with you my concern that responsible prescribing guidelines for atypical anti-psychotics developed by VA practitioners were being mischaracterized as a barrier that would prevent physicians from prescribing drugs they believe will best meet patients' clinical needs. Opponents of VA's guidelines have unfairly portrayed them as preventing physicians from prescribing drugs they believe will best meet patients' clinical needs, i.e., they have referred to the guideline as a "fail-first policy". VA does not have a fail-first policy. Any inference that one exists is simply untrue. VA physicians are free to prescribe any medication included on the VA formulary. What is being inaccurately described as a fail-first policy is nothing more or less than sound, cost-effective, clinical decision-making, with a mechanism for beginning treatment with an effective, less expensive agent.

Mr. Chairman, I believe VA is in the forefront of health care providers in integrating the provision of pharmaceuticals in its patient treatment programs. By placing first priority on patient needs; by emphasizing disease prevention; by implementing best clinical practices; by assessing validated evidence of a pharmaceutical product's effectiveness; and by employing national procurement strategies whenever clinically possible—VA is providing high quality care and doing so in a cost effective manner. We are proud of our successes and the contributions these efforts are making to the Nation's understanding of health care delivery.

This completes my statement. I will be happy to respond to questions from the Committee.

ATTACHMENT—CHRONOLOGY OF SIGNIFICANT ACCOMPLISHMENTS IN PHARMACY BENEFITS MANAGEMENT 1988 TO PRESENT

1988—National IV Solution Contract, VA's first large standardization contract.

1989—Establishment of Veterans Health Administration (VHA) liaison with VA's National Acquisition Center.

1990—Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) linked VA pricing to the best prices paid in the Medicaid program.

1991—VHA established Drug and Pharmaceutical Product Management Working Group. VA developed the concept of Federal Pharmacy as it related to service delivery and contracting for pharmaceuticals.

1992—Passage of Public Law 102–585, sections 601, 602, and 603 of which addressed the higher prices paid by VA and other government buyers as a result of OBRA '90. VA began the Consolidated Mail Outpatient Pharmacy (CMOP) pilot program.

1993—Full conversion to the Pharmaceutical Prime Vendor drug distribution system.

1994—Accelerating change: commitment of the USH as described in the Vision for Change. Full activation of VA's first automated CMOP facility.

1995—Establishment of VHA's Pharmacy Benefits Management Strategic Healthcare Group.

1996—Commercial Practice Initiative for National Contracts. Drug Treatment Guidelines in development.

1997—Implementation of VA's National Formulary Process. Additional drug treatment guidelines developed.

1998—VA/DOD Joint Procurement Activities. Establishment of the Federal Pharmacy Executive Steering Committee (FPESC). PBM database links prescription utilization to patients and providers. Enhanced PBM website.

1999—PBM received an award as a Finalist in the annual Rochester Institute of Technology/USA Today Quality Cup Competition for its overall contribution to quality movement. GAO published study "VA HEALTHCARE: VA's Management of Drugs on Its National Formulary," GAO/HEHS–00–34.

2000—Institute of Medicine Report analyzes the VA National Formulary process ("Description and Analysis of the VA National Formulary").

2001—Data mining capability of the PBM's national utilization database made available to all VISNs. GAO reports validate the VA National Formulary Process ("VA DRUG FORMULARY: Better Oversight Is Required, but Veterans Are Getting Needed Drugs," GAO–01–183; "DOD and VA Pharmacy: Progress and Remaining Challenges in Jointly Buying and Mailing Out Drugs," GAO–01–588).

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. JOHN D. ROCKEFELLER IV TO ANTHONY J. PRINCIPI

Question 1. It's clear how VA's increase to $7 for the drug co-payment is being justified, when compared with benefits offered by private sector health plans. However, while $7 per prescription is less than what most Americans pay for their medications, the increase will certainly cause a hardship for many veterans. Were other amounts—or a sliding scale—considered? On what basis was the determination made to set the co-payment at $7?

Answer. A work group within the Veterans Health Administration reviewed the co-payment structure for medication co-payments. The work group engaged the services of a contractor to perform a literature search on co-payments charged by the private sector. A review of the literature from 1996 showed that 96 percent of health maintenance organization (HMO) enrollees have a prescription co-payment ranging from $5 to $10 per prescription. The work group requested an update of these data, and the 2000 information showed that co-payment amounts were now ranging from $10–$15. This was due in part to new cost-sharing product designs and the rising cost of health care in general.

Based on a review of industry standards, VA believes that the medication co-payment should be increased from $2 to $7. The $7 medication co-payment is lower than or equal to most medication co-payments charged by the private health care industry. The co-payment amount is a reasonable amount for the majority of medications dispensed. VA does recognize that veterans in certain priority groups may be in need of multiple medications. To try to minimize their out-of-pocket expenses, VA is implementing an annual cap of $840 for veterans in priority groups 2–6. When the annual cap is met, the veteran will not be charged medication co-payments until the beginning of the next calendar year. VA is not implementing an annual cap for veterans enrolled in priority group 7. The final regulations for the medication co-payment were printed in the Federal Register on December 6, 2001. The increase in the medication co-payment amount and the annual cap will be implemented on February 4, 2002.

Question 2. The published regulation on the copayment increase states that VA incurs an average cost of more than $7 dollars to fill a prescription—and that's just the administrative cost of dispensing the prescription to the veteran, not the medication itself. States' dispensing fees under Medicaid average between $4 and $5, and

they are even lower in the private sector. Why are VA's dispensing costs so high in comparison?

Answer. The State dispensing fees cited above are payments made by State Medicaid programs to participating pharmacies and have never covered the actual dispensing costs of a prescription. There have been numerous lobbying efforts by State Pharmaceutical Associations to raise these dispensing fees to cover the actual cost of dispensing a prescription. Nationally, the American Pharmaceutical Association, the National Association of Chain Drugstores, and other associations also continue to lobby for changes.

The $7.28 dispensing cost reported by VA for FY 2001 represents the personnel time to procure the drug, inventory costs, overhead such as lighting and maintenance, management and oversight, depreciation of equipment, and the pharmacist's time to actually dispense and consult with the patient. The cost of the drugs purchased by VA represents the actual purchase price and not the discounted AWP (average wholesale price) VA would have to pay if it purchased prescriptions through an insurance mechanism. Prescriptions provided in that manner would be substantially higher in cost than prescriptions provided directly by VA pharmacies.

Question 3. Congress authorized VA to increase the drug copayment and decrease the outpatient copayment from $50 to a more reasonable amount. Congress was quite clear about this, even recommending that VA not set a single copayment rate for outpatient care, but instead consider practices within the health care industry to differentiate between primary care and specialty clinic visits. While VA has produced the drug copayment regulations, the regulations on the outpatient copayment have not yet been published. Why weren't these copayment changes made concurrently?

Answer. Interim final regulations to implement changes to the outpatient co-payment were published in the Federal Register on December 6, 2001, and were effective immediately. A three-tiered co-payment structure is being implemented. The co-payment amount will be based upon the level of service provided (i.e., primary care versus specialty care). Even though the medication co-payment is being increased, VA believes that the reduced outpatient co-payment will partially offset this increased expense for our patients.

Question 4. VA's decision to enroll category 7 veterans is made at the beginning of each fiscal year. What is your current thinking on cutting off enrollment for new Category 7 veterans?

Answer. The Administration has determined to continue enrolling veterans in all priority groups during FY 2002.

Question 5. Again and again, as the Committee addresses VA health care issues, the devolution of power to the health networks becomes a focal point. Problems with a lack of national oversight in the area of quality management and specialized services have already been highlighted. And the Institute of Medicine's (IOM) testimony recommended that the formulary structure should be "recalibrated towards a more uniform national approach" so as to cease further inequities in the local formularies.

Please share your thoughts on the network structure generally and on the IOM recommendation specifically.

Answer. The Veterans Integrated Service Network (VISN) structure was created in 1995. It integrates decentralization of daily operations with the opportunity to better align resources with local needs and improve service delivery. Nonetheless, given this flexibility to address local needs, other mechanisms assure that requirements of vital national programs are addressed equitably across the system. National Performance Measures and Monitors are developed to address such health care issues as patient safety, clinical practice guidelines, special emphasis programs (prosthetics, Spinal Cord Injury, etc.) and waiting times, to name just a few. The measures and monitors have identified goals and are clearly communicated to all networks at the beginning of each fiscal year. Furthermore a national committee reviews the measures and monitors on an annual basis to modify, add, or delete elements to assure that important health care issues are addressed and current.

VA concurs with the recommendation of the IOM concerning a recalibration towards a more uniform approach to formulary management. With over 90 percent of all outpatient prescriptions written for items listed on the VA National Formulary (VANF), VA has made considerable progress since the inception of the VANF process in 1997. Prior to 1997, the rate of variation across the formularies of the local VA medical facilities was much greater than in the current environment. While much progress has been made, VA will continue to refine the VANF process by directing that local formularies will no longer be authorized under the new VAN F policy directive. In addition, the new directive will outline specific procedures for adding new drugs to the VANF so that the potential for inter-VISN variation is greatly reduced. These policy changes and other changes concerning the consistent

provision of prescribed medications for patients who relocate from one region of the country to another and new requirements for access to non-formulary drugs will help to reduce variability and ensure continuity of therapy for VA patients.

Chairman ROCKEFELLER. In looking at my witness list here, Mr. Griffin, you were going to make some comments, also, were you not?

Mr. GRIFFIN. Yes, that is correct.

Chairman ROCKEFELLER. We look forward to those.

STATEMENT OF RICHARD J. GRIFFIN, INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY MICHAEL SLACHTA, JR., ASSISTANT INSPECTOR GENERAL FOR AUDITING

Mr. GRIFFIN. Mr. Chairman and members of the committee, I am here today to report on our audit of the Veterans Health Administration restrictions on filling privately written prescriptions. This issue was addressed in our audit report issued on December 20 of 2000.

Full implementation of our recommended actions would provide the Department of Veterans Affairs with cost efficiencies by streamlining the process of providing privately written prescriptions for pharmaceuticals. Efficiencies would be gained by eliminating redundant medical examinations that cost the Department over $1.3 billion annually and reducing the overcrowding of some clinics.

The Veterans Health Care Eligibility Reform Act of 1996 required VA to enroll veterans annually according to seven priority groups. Once enrolled, all veterans, regardless of their priority grouping, have access to all of the health services in VA's basic medical benefits package, which includes prescription drugs and supplies.

Priority group seven is comprised of veterans without compensable service-connected disabilities and with incomes above prescribed limits. These veterans are subject to a $2 copayment for each 30-day supply of prescribed medications obtained from VA. Use of VA's prescription drug benefit provides these veterans with the opportunity to obtain prescriptions at a significantly lower cost, since their private insurance generally excludes this benefit.

We assessed the extent that priority group seven veterans use pharmacy services from VISN 8 medical facilities for the sole or primary purpose of filling privately written prescriptions. To do so, we identified veterans who had at least one visit to a Network 8 facility during fiscal year 1999 and at least four active prescriptions during that same year. We reviewed the records for a sample from this group and found that almost 90 percent had access to private non-VA health care or there was a clear statement in the medical record that their sole or primary reason for using the VA was to have private prescriptions filled.

Based on the case review results, we estimated that in fiscal year 1999, 46,866 of the network's 52,570 priority group seven veterans had access to private non-VA health care and used VA health care services to have private prescriptions filled.

VA regulations do not allow VA pharmacies to fill prescriptions issued by private physicians, except in limited circumstances, such

as for veterans who are house-bound or are receiving Aid and Attendance benefits from VA. Veterans holding privately written prescriptions are scheduled for examinations by VHA staff physicians, who routinely duplicate tests that were already performed by the patient's private physician. Their prescriptions are then filled by the VHA pharmacy if the drugs are listed on VA's drug formulary. When not listed in the formulary, an alternative is issued in consultation with the private physician.

Indirect costs of validating prescriptions written by private physicians include the staff and clinic time associated with completing the exams and any clinical tests that might be required. We estimated that VISN 8 spent almost $114 million in fiscal year 1999 following this process.

VHA's process also adds to the already overcrowded conditions and extended waiting times that exist in some clinics. The managers and clinic staff we spoke with during the audit acknowledged that a more efficient and streamlined process was needed, but they were hampered due to the existing VA regulations that require a veteran to be under VA care in order to receive prescription drugs.

We recommended that VA seek the statutory and regulatory authority to fill private prescriptions written for enrolled veterans and that appropriate quality assurance systems be implemented to ensure VA-filled prescriptions were appropriate and safe. The Under Secretary for Health deferred a decision and indicated that the issue needed to be considered by VHA's Leadership Board. At this time, the recommendation remains unresolved, pending the outcome of the board's deliberations and the Under Secretary's decision.

This concludes my oral testimony. I would be pleased to answer any questions that you and your members might have.

Chairman ROCKEFELLER. Thank you, Mr. Griffin, very much.

[The prepared statement of Mr. Griffin follows:]

PREPARED STATEMENT OF RICHARD J. GRIFFIN, INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairman and Members of the committee, I am here today to report on our audit of the Veterans Health Administration (VHA) restrictions on filling privately written prescriptions. On December 20, 2000 we issued an audit report to the Under Secretary for Health identifying opportunities to reduce the costs of providing prescriptions to priority group 7 veterans and make additional resources available for veterans healthcare.* Full implementation of our recommended action would provide the Department of Veterans Affairs (VA) with cost efficiencies exceeding $1.3 billion annually.

The streamlining of the process of re-writing privately written prescriptions for pharmaceuticals would reduce the overcrowding of some clinics. Further, many veterans would no longer need to experience the frustration of going through the process of scheduling exams and tests that frequently duplicates the examinations they received from their private physicians. During our audit we found that as many as 90 percent of the priority group 7 veterans have access to private non-VA healthcare and use VA for the sole or primary purpose of filling privately written prescriptions.

PRIORITY GROUP 7 USE OF VHA'S PHARMACEUTICAL BENEFIT

The "Veterans Health Care Eligibility Reform Act of 1996" required VA to enroll veterans annually according to seven priority groups. Once enrolled, all veterans, re-

*The report, Audit of Veterans Health Administration Pharmacy Co-Payment Levels And Restrictions On Filling Privately Written Prescriptions For Priority Group 7 Veterans, is available on the VA Office of Audit web site at http://www.va.gov/oig/52/reports/maillist.htm: List of Available Reports

gardless of their priority grouping, have access to all of the health services described in VA's basic Medical Benefits Package, which includes prescription drugs and supplies. Priority group 7 is comprised of veterans without compensable service-connected disabilities and with incomes above prescribed limits. These veterans are subject to a $2 co-payment for each 30-day supply of prescribed medications obtained from VA. With the low $2 co-payment, most of the priority group 7 veterans in the Veterans Integrated Service Network (VISN) 8 used VA for the sole or primary purpose of filling prescriptions from their private physicians. Use of VA's prescription drug benefit provides these veterans with the opportunity to obtain prescriptions at a significantly lower cost since their private insurance generally excludes this benefit.

To assess the extent that priority group 7 veterans used pharmacy services from VISN 8 medical facilities for the sole or primary purpose of filling privately written prescriptions, we identified veterans who had at least (i) one visit to a network facility during FY 1999 and (ii) four active prescriptions during that same year. We reviewed the records for a sample from this group and found that almost 90 percent had access to private non-VA health care and/or there was a clear statement in the medical record that their sole or primary reason for using VA was to have private prescriptions filled.

Based on the case review results, we estimated in Fiscal Year (FY) 1999 that 46,866 of the Network's 52,570 priority group 7 veterans had access to private non-VA healthcare and used VA healthcare services to have private prescriptions filled. We estimated that VHA-wide 361,698 of the 405,718 priority group 7 veterans used VA health care services in FY 1999 to have their private prescriptions filled.

THE PROCESS USED FOR FILLING PRIORITY GROUP 7 VETERANS PRESCRIPTIONS WRITTEN BY PRIVATE PHYSICIANS IS INEFFICIENT

VA regulations do not allow VA pharmacies to fill prescriptions issued by private physicians except in limited circumstances (e.g., for veterans who live in Alaska, are housebound or are receiving Aid and Attendance benefits from VA). However, we found that veterans holding privately written prescriptions are scheduled for medical examinations by VHA staff physicians who routinely review and approve the orders of the private physicians. These prescriptions are then filled by the VHA pharmacy if the drugs are listed in VA's drug formulary. When not listed in the formulary, a substitute or alternative is issued in consultation with the private physician. We found that the VA's medical examinations frequently duplicate tests and procedures that were already performed by the patient's private physician and were conducted to allow the VA physician to support a prescription that the patient had from his or her private physician.

Indirect costs of re-writing private prescriptions include the staff and clinic time associated with completing the medical examinations and tests that allow VA physicians to re-issue the prescription. We estimated that VISN 8 spent almost $114 million in FY 1999 following this process. Although some of the costs were recouped through billing veterans insurance companies for outpatient visits, the exact amount of the recoupment could not be determined because inpatient and outpatient collections were not separately identified by VHA. We estimated that VHA-wide as much as $1.33 billion would be spent in FY 2001 completing medical examinations and tests.

In addition to the costs of performing the necessary examinations and tests needed to validate privately written prescriptions, VHA's process also adds to the already overcrowded conditions and extended waiting times that exist in some clinics. The managers and clinical staff we spoke with during the audit acknowledged that a more efficient and streamlined process was needed, but they were hampered due to the existing VA regulations that required the tests and examinations. We recommended that VA seek the statutory and regulatory authority to fill private prescriptions written for enrolled veterans and that appropriate quality assurance systems be implemented to ensure VA-filled prescriptions were appropriate and safe. The Under Secretary for Health has indicated that VHA's National Leadership Board will consider this issue and deferred agreement with the recommendation. At this time the recommendation remains unresolved, pending the outcome of the Board's deliberations and the Under Secretary's decision.

This concludes my testimony. I would be pleased to answer any questions that you and the members of the committee may have.

Chairman ROCKEFELLER. At a 1999 hearing, the then-Under Secretary for Health was asked if there was any indication that Medicare-eligible veterans were turning to the VA for prescription

drugs, and at that time, 2 years ago, he answered, "I can't quantify it in precise dollars, but it is a generally recognized phenomena that it is occurring across the country and for very understandable reasons." He went on to say, "I would expect that it is in the hundreds of millions of dollars in terms of range."

Mr. SECRETARY AND MR. Griffin, how would you update that, or Dr. Garthwaite, whoever.

Dr. GARTHWAITE. I don't think we have any disagreement with Mr. Griffin's study, although I think VISN 8 is a tough one to extrapolate for the rest of the United States because of the rapidity of growth that we have seen in the number of veterans accessing the system down there. There are, I think, 40,000 new unique patients coming in just this year.

Our challenge has been that we believe we are not allowed to just simply fill prescriptions and so we have tried to stay out of the pharmacy business. We also don't want to be competing against private pharmacies. We don't think that is our function, either. And we also believe we need to coordinate the care and concur with the prescriptions that these patients get from their non-VA providers. We do, however, believe strongly that the lack of coordination of benefits amongst the various Federal and private systems causes patients to experience a fair amount of confusion. The fact that they seek care from us is, as you said, totally understandable.

Chairman ROCKEFELLER. Which leads directly to my next question. If the VA were authorized to provide pharmaceuticals that had been prescribed by non-VA doctors, what do you think would be the condition and situation of the Department of Veterans Affairs 5 to 8 years from now?

Mr. PRINCIPI. I believe that cost would dramatically rise. Obviously, I think a great many more veterans would come to the VA just to have their prescriptions filled, especially with our very efficient consolidated mail-out pharmacy program. You don't have to drive 100 miles to a VA medical center and wait for hours to have a prescription filled anymore. You can go once, and hopefully now with all the outpatient clinics close by they are very readily accessible, and get the first prescription filled locally, and then from that point on, they are mailed to your home. So I think it would increase it dramatically.

But what concerns me more is that we have been effective in establishing a national formulary. I don't know how you would manage that if every provider or physician in America could write a prescription that would be filled by the VA and how you would manage how they would know what is on our national formulary. I think it would be a management challenge to control the formulary.

Chairman ROCKEFELLER. There would be some concern whether or not the VA would become a pharmacy?

Mr. PRINCIPI. Well, we would become a pharmacy.

Chairman ROCKEFELLER. Yes.

Mr. PRINCIPI. I don't think there is any question about it. I understand the sentiment from where the Inspector General is coming from. I just think it would be very, very difficult to manage and that we would, in fact, become a pharmacy.

Mr. GRIFFIN. Mr. Rockefeller, if I may——

Chairman ROCKEFELLER. Yes, sir?

Mr. GRIFFIN. If a person goes to Johns Hopkins and gets a prescription, they are free to take that to any pharmacy they want to go to and that pharmacist does not have another doctor validate that prescription. What we projected here on a national basis is $1.3 billion worth of medical care that is being spent, if you will, for this purpose which could be utilized to address more serious problems of other veterans.

We are not supporting the concept of the VA as a pharmacy. What our report addresses is priority seven veterans and whether or not it makes sense to redo those examinations that are done by another doctor at the expense of other things that those health care providers could be doing.

Chairman ROCKEFELLER. And I understand that, and I thank you, sir.

Just one more question before my time expires. Pharmaceuticals are very expensive no matter what, and getting more so. I would suppose so. It will be very interesting to see what we do in the non-VA prescription drug cost containment area. It is very controversial.

But I know one of the things that you have been very good at in the VA is contracts for generic drugs. What is important about that is it is not just the lower cost that is important, it is also the quality that is important and we have to keep bearing that in mind.

Now, I understand that for some time now, the VA has been attempting to contract for Clozapine, which is used to treat schizophrenia. Apparently, there appear to be delays related to protests which, understandably and predictably, come from those who don't want to see a generic used. I am concerned, however—and that is not the VA's fault. The VA has nothing to do with that. But I am concerned that the VA may inadvertently be exacerbating the delay—I am not sure of that, but I am interested in that—even after protests are denied, by beginning the negotiations all over again. In other words, the VA starts the system up again. This question may be for the IG.

My question is, No. 1, what is the reason, unless it is too specific a question, for the delay, and almost regardless of your answer, I would like to be able to get a white paper of some sort on that particular problem, because it foretells the future.

Mr. OGDEN. This is a good example where protests, and I am not a contracting officer nor am I a contracting attorney, but this is a good example where the Federal procurement regulations can be used against us, so to speak. Your comment, Senator Rockefeller, about the possibility that we in VA might be not in favor, if you will, of a generic contract in the area of clozapine, I can tell you that, as you well know, our system is based on the use of generic drugs, and if we could use a generic clozapine, we would use it and we would have awarded the contract by now.

But during the process of developing the contract solicitation and through the last couple of years, there have been a number of protests, but there has also been some evidence presented that the conversion from the branded product, a generic clozapine in some cases hasn't been successful. So our mental health professionals

who work with us in evaluating this solicitation were a little hesitant to move forward at a point in time, but notwithstanding that, that is the primary reason, if you want to describe that we were not in favor of a generic, that is the primary reason. But we will award the generic contract if and when the General Accounting Office denies this latest protest, and assuming we don't have any other protests in the near future.

Chairman ROCKEFELLER. OK. If I could get something in writing on that, I would appreciate it very much.

Senator Specter?

Senator SPECTER. Thank you, Mr. Chairman.

Mr. Secretary, financing prescription drugs is very costly. I need to ask you many questions but there is such a limited period of time that it may be advisable for you to supplement your responses. I am not going to be able to be here for the second round. I have other commitments and I will have to excuse myself.

When you talk about the efficiencies of joint contracting by DoD and VA, what would be the projection on economies if Medicare was put into the mix? Wouldn't it be quite considerable?

Mr. PRINCIPI. I think it would probably increase our costs somewhat. I doubt we could sustain the discount levels that we receive if Medicare was consolidated with us.

Senator SPECTER. Well, why would that be? The pharmaceutical companies are not selling to you at a loss at the present time, are they?

Mr. PRINCIPI. No, but we get a significant discount. Let me ask the head of Pharmacy Service perhaps if he would have any estimates on how much we could save, or if not, I will provide it for the record.

Mr. OGDEN. If I understand your question correctly, if we included Medicare, DoD, and VA under the same umbrella and then subsequently went out and acquired contracts, what would be the impact, up or down, on the system, on our system, or even the DoD system? My sense is that we would see increased pricing for the Department of Veterans Affairs and the Department of Defense, and the reason I say that is because of past experience with OBRA 1990, et cetera, but also the Medicare market is huge, potentially huge out there, and a lot of those drug dollars, those expenditures for those drugs is already in the economy. So what you would in essence be doing would be to affect the bottom line of the pharmaceutical industry pretty significantly, because right now, the VA and DoD is about 3 percent of the U.S. market.

Senator SPECTER. That might be something that would lend itself to a good Congressional investigation, maybe from this committee. I know the costs are very high in the Medicare community, but it is a matter of straightforward logic that if there are greater quantities—the costs of pharmaceuticals are a very flexible item. We see all sorts of surprising practices.

Pharmaceuticals are sold in Canada at a lower cost than here, and we have a tremendous controversy about people from the border States going into Canada to buy drugs. We have had quite a legislative battle on that. We have had the issue of pharmaceuticals for AIDS, where the pharmaceutical companies have made modifications in their prices.

And the Medicare community may have, to some extent, a differing prescription demand, but I would like you to make a study of it, Mr. Ogden and Mr. Secretary, as to the impact, because the logic is all in favor of joint contracting. Just as you get a lower cost if DoD and VA get together, you ought to get a lowest cost if you add a third agency to the mix, Medicare. And there is enormous public concern and Congressional concern about the cost of pharmaceuticals.

This all works into a very, very complex question about patent rights, and about patent extensions, and about orphan drugs—issues the pharmaceutical companies bring to the Judiciary Committee all the time. And then there is the issue of generic drugs, and the issue which we have talked about considerably as to Medicare subvention We have enormous budget battles every year about how much Medicare is going to get as opposed to how much the veterans are going to get. While it is true that we are taking money out of two pockets in the same pair of pants, still, those allocations need to be made. VA needs Medicare subvention.

So what I would like to see done is an analysis as to the feasibility of the Veterans Administration getting a reimbursement from Medicare, which may have a better constituency when budget time comes around than we are able to get for the veterans. And I would like you to then carry over that analysis into pharmaceuticals and see what can be done—perhaps a little jawboning, anatomically speaking—even a little arm twisting over prices when the Federal Government gets into prescription drug purchasing in a big way. I think we have got to get just a little bit tough here when we are going to be putting a lot of money into currency which will benefit the pharmaceutical companies.

And then to throw in one more line—but just one more since the red light is now on—I raise the issue of NIH subsidization. NIH subsidizing drug companies—enormously, we have increased NIH funding from $12 billion to $20.5 billion and soon it will be $24 billion. So I think we can look to the pharmaceutical companies to pay a little attention to veterans and to Medicare and I would like to see us start off to get some answers to some pretty pointed questions.

Mr. PRINCIPI. We will provide that for the record.

[The information referred to follows:]

REPORT TO CONGRESSIONAL REQUESTERS—AUGUST 2000

PRESCRIPTION DRUGS—EXPANDING ACCESS TO FEDERAL PRICES COULD CAUSE OTHER PRICE CHANGES (GAO/HEHS–00–118)

ABBREVIATIONS

AMP average manufacturer price
AWP average wholesale price
CBO Congressional Budget Office
DOD Department of Defense
FCP federal ceiling price
FSS federal supply schedule
GSA General Services Administration
HCFA Health Care Financing Administration
HMO health maintenance organization
HRSA Health Resources and Services Administration
OBRA Omnibus Budget Reconciliation Act of 1990
NFAMP nonfederal average manufacturer price

PHS Public Health Service
VA Department of Veterans Affairs

B–284570
August 7, 2000.

The Honorable TOM BLILEY,
Chairman,
Committee on Commerce,
House of Representatives.

The Honorable MICHAEL BILIRAKIS,
Chairman, Subcommittee on Health and Environment,
Committee on Commerce,
House of Representatives.

Federal departments and agencies can purchase prescription drugs at substantial discounts off market prices through the federal supply schedule (FSS) for pharmaceuticals. Administered by the Department of Veterans Affairs (VA), the FSS for pharmaceuticals is a list of products and their prices that are available to federal entities that purchase prescription drugs.[1] During fiscal year 1999, federal purchasers spent over $2.75 billion on prescription drugs,[2] about $1.5 billion of which was for drugs purchased from the FSS. Also, federal law guarantees substantial drug price discounts to state Medicaid programs and specific public health entities that receive federal assistance.

As the Congress considers adding a prescription drug benefit to Medicare, there is increased interest in understanding the ways that government purchasers have controlled their costs for prescription drugs and whether these methods can be used to reduce prescription drug costs for Medicare beneficiaries. One proposal before the Congress would allow Medicare beneficiaries to purchase drugs from pharmacies at the same prices that are available to federal purchasers or state Medicaid programs. Because of your Interest in the issue of expanding Medicare beneficiaries' access to prescription drugs, you asked us to provide you with information on (1) the federal drug price discounts available to federal and nonfederal purchasers and the size of those discounts, and (2) the potential effects that extending such discounts to nonfederal purchasers may have on outpatient drug prices paid by federal and nonfederal purchasers.

To address these issues, we obtained information on the drug purchasing methods and prices available to the federal departments and agencies that spend the most on prescription drugs—VA, DOD, and the Public Health Service (PHS). We also obtained information from the Health Care Financing Administration (HCFA) on the rebates state Medicaid programs receive through the Medicaid drug rebate program. In addition, we contacted officials of the Health Resources and Services Administration's (HRSA) Office of Drug Pricing to determine the drug price discounts available to public health entities that receive federal assistance.[3] Further, we reviewed several studies relevant to the potential impact of expanding the availability of government drug price discounts to nonfederal purchasers. We conducted our study between December 1999 and June 2000 in accordance with generally accepted government auditing standards.

RESULTS IN BRIEF

Federal departments and agencies, state Medicaid programs, and numerous nonfederal public health entities have access to prescription drugs at substantially lower prices than many other purchasers. Federal entities can purchase drugs from the FSS at prices that are the same or lower than those drug manufacturers charge their most-favored private purchasers. Under federal law, drug manufacturers must list their brand-name drugs on the FSS to receive reimbursement for drugs covered by Medicaid.[4] Manufacturers must also sell brand-name drugs listed on the FSS to four federal purchasers—VA, DOD, PHS, and the Coast Guard—at a price at least 24 percent lower than the nonfederal average manufacturer price (NFAMP), a ceil-

[1] The FSS may list the same drug in different dosage amounts and package sizes. Each listing is considered an individual item or product.

[2] This total includes all FSS sales to federal purchasers, as well as non-FSS sales associated with contracts VA and the Department of Defense (DOD) have with drug manufacturers.

[3] The Office of Drug Pricing is now called the Office of Pharmacy Affairs.

[4] See 38 U.S.C. sec. 8126, as added by the Veterans Health Care Act of 1992 (P.L. 102–585, sec. 603).

ing price that is lower than the FSS price for many drugs.[5] In addition, VA has obtained some drug prices that are even lower than FSS prices through national contracts based on a competitive-bid process. On average, these contracts have resulted in prices that are about one-third lower than corresponding FSS prices. Federal law also specifies that state Medicaid programs and certain nonfederal purchasers can receive substantial discounts on prescription drug prices. Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), drug manufacturers must provide rebates to state Medicaid programs for their outpatient drugs in exchange for Medicaid coverage.[6] For brand-name drugs, the minimum rebate is 15.1 percent of the average manufacturer price (AMP).[7] During fiscal year 1999, the rebates state Medicaid programs collectively received amounted to about 19 percent of overall payments for prescription drugs. The Public Health Service Act also provides some nonfederal purchasers, such as community health centers and certain public hospitals, access to drug prices based on Medicaid rebates.

Mandating that federal prices for outpatient prescription drugs be extended to a large group of purchasers, such as Medicare beneficiaries, could lower the prices they pay but raise prices for others. Such price changes could occur because drug manufacturers would be required to charge beneficiaries and federal purchasers the same prices. To protect their revenues, manufacturers could raise prices for federal purchasers. Furthermore, because federal prices are generally based on prices paid by nonfederal purchasers, manufacturers would have to raise prices to these purchasers in order to raise the federal prices. In particular, large private purchasers that tend to pay lower prices, such as health maintenance organizations (HMO) and other insurers, could see their prices rise. While it is not possible to predict the extent or timing of any changes in manufacturer pricing strategies if Medicare beneficiaries gained access to the same prices available to federal purchasers, the experience following implementation of a Medicaid rebate suggests that manufacturers would adjust prices quickly. The magnitude of these potential effects would vary by drug and would depend on a number of factors, including the relationship between the specific federal price extended to Medicare beneficiaries and the price paid by nonfederal purchasers, as well as the number of Medicare beneficiaries with access to the federal price.

BACKGROUND

Prescription drug expenditures have increased substantially in recent years.[8] From 1993 to 1998, prescription drug spending grew at an average rate of 12.4 percent per year, compared with a 5 percent average annual growth rate for health care expenditures overall. As a result, prescription drugs account for a growing share of total health care spending, rising from 5.6 percent in 1993 to 7.9 percent in 1998. This dramatic rise in drug outlays has occurred for a number of reasons, including greater utilization of drugs, the substitution of higher-priced new drugs for lower-priced existing ones, and more direct-to-consumer advertising of drugs by manufacturers.

In the face of increasing drug expenditures, large purchasers attempt to control their drug costs, in part, by negotiating lower prices with manufacturers. Some purchasers deal directly with manufacturers while other purchasers have representatives that act on their behalf. For example, pharmacy benefit managers negotiate drug prices for many HMOs and insurers, while group purchasing organizations representing thousands of the nation's hospitals do the same. The leverage purchasers bring to negotiations is based largely on their ability to increase the volume used of a particular drug through mechanisms that influence physicians' prescribing and enrollees' purchasing practices. Using these mechanisms, they can offer manufacturers a larger volume of sales in exchange for bigger discounts.

To control which specific drug products they will purchase and the volume used, HMOs and other insurers frequently create a formulary. A formulary is a list of drugs, grouped by therapeutic class, that a purchaser prefers its physicians to pre-

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[5] The NFAMP is the weighted average price of each single form and dosage unit of a drug that is paid to a manufacturer by wholesalers for nonfederal purchasers, taking into account any cash discounts or similar price reductions.

[6] See P.L. 101–508, sec. 4401.

[7] The AMP is the weighted average price of each form and dosage unit of a drug that is paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, taking into account cash discounts or similar price reductions. FSS prices and prices associated with direct sales to HMOs and hospitals are excluded from this calculation.

[8] See *Prescription Drugs: Increasing Medicare Beneficiary Access and Related Implications* (GAO/T–HEHS/AIMD–00–100, Feb. 16, 2000). From 1993 to 1998, national expenditures for prescription drugs grew from about $50.6 billion to about $90.6 billion.

scribe because of the drugs' medical value and price. Because there are often similar products competing for a share of the market, the greater the purchaser's ability to determine which products it will include on its formulary, the more leverage the purchaser has to exact lower prices from manufacturers.[9] The purchaser can influence utilization by encouraging physicians to prescribe lower-cost formulary drugs over both higher-cost formulary and nonformulary drugs. The purchaser may also provide financial incentives, such as reduced copayments, to encourage its health plan members to request that physicians prescribe lower-cost formulary drugs, including generics.[10]

FEDERAL PRICE DISCOUNTS ON PRESCRIPTION DRUGS ARE SIGNIFICANT FOR FEDERAL AND NONFEDERAL PURCHASERS

Federal law enables the federal government to use its leverage as a large purchaser of prescription drugs to secure some of the lowest prices available for pharmaceuticals. Through the FSS and the Medicaid rebate programs, manufacturers must provide many of their drugs at significantly discounted prices in exchange for having their drugs covered by Medicaid. Federal law also sets a ceiling price on FSS brand-name drugs purchased by select federal purchasers and extends prices based on Medicaid rebates to many public health entities that receive federal assistance. In addition, VA has been able to obtain some prices even lower than FSS prices through national contracts with drug manufacturers that channel utilization to specific products.[11] Table 1 describes various federal drug prices available to federal and nonfederal purchasers and their relationship to benchmark prices.

Table 1: Pharmaceutical Pricing Terms

Price	Definition
Retail price	The price charged by retail pharmacies to individuals without insurance, known as "cash-paying" customers.
Average wholesale price (AWP)	The average list price that a manufacturer suggests wholesalers charge pharmacies. AWP is typically less than the retail price, which will include the pharmacy's own price markup. AWP is referred to as a sticker price because it is not the actual price that large purchasers normally pay. For example, in a study of prices paid by retail pharmacies in 11 states, the average acquisition price was 18.3 percent below AWP.[a] Discounts for HMOs and other large purchasers can be even greater. AWP information is publicly available.
AMP	The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. FSS prices and prices associated with direct sales to HMOs and hospitals are excluded. AMP was a benchmark created by OBRA in 1990 to use in determining Medicaid rebates and is not publicly available. The Congressional Budget Office (CBO) estimated AMP to be about 20 percent less than AWP for more than 200 drug products frequently purchased by Medicaid beneficiaries.[b]
NFAMP	The average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers. NFAMP is not publicly available.
FSS	The price available to all federal purchasers for drugs listed on the FSS. FSS prices are intended to equal or better the prices manufacturers charge their "most-favored" nonfederal customers under comparable terms and conditions. Because terms and conditions can vary by drug, the most-favored customer price may not be the lowest price in the market. FSS prices are publicly available.
Federal ceiling price (FCP)	The maximum price manufacturers can charge for FSS-listed brand-name drugs to VA, DOD, PHS, and the Coast Guard, even if the FSS price is higher. FCP must be at least 24 percent off NFAMP. FCP is not publicly available.

[9] Competition can exist between brand-name drugs that are therapeutically equivalent, between brand-name drugs and generic substitutes, and between generic versions of the same drug. Brand-name or innovator drugs generally have a patent on their chemical formulation or on their manufacturing process. While under patent protection, they are called single-source drugs because only the company that holds the patent produces them. After the patent has expired, generic copies of the exact chemical formulation usually become available and the drugs are then referred to as multiple-source drugs.

[10] Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs.

[11] VA refers to these as committed-use contracts.

Table 1: Pharmaceutical Pricing Terms—Continued

Price	Definition
Medicaid rebate net price	The effective outpatient drug price after manufacturer rebates to state Medicaid programs. The basic rebate on brand-name drugs is the greater of 15.1 percent of the AMP or the difference between AMP and the lowest or "best" price the manufacturer charges any purchaser other than Medicaid. Rebates for generic drugs are 11 percent of the AMP. Rebates are larger for brand-name drugs whose AMP increases exceed inflation in the consumer price index. Information on rebate amounts is publicly available; AMP and best price are not.
VA national contract price	The price VA has obtained through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Contract prices are publicly available.

[a] See Office of the Inspector General, ***Medicaid Pharmacy—Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs*** (Washington, D.C.: HHS, Apr. 1997).
[b] See ***CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*** (Washington, D.C.: CBO, Jan. 1996, p. 20).

FSS and Ceiling Prices

The FSS for pharmaceuticals contains over 17,000 products available to federal departments, agencies, institutions, and several other entities, such as the District of Columbia, U.S. territorial governments, and numerous Native American tribal governments. VA is responsible for administering the FSS and is also the schedule's largest purchaser—about $1.2 billion in fiscal year 1999, representing almost 83 percent of all sales at FSS prices. According to VA, during fiscal year 1999, FSS drug sales totaled about $1.5 billion—about 1.1 percent of domestic pharmaceutical sales.[12]

Although manufacturers are not required to list their drug products on the FSS, they have financial incentives to do so despite the FSSs relatively low prices. Manufacturers are required to list their brand-name products on the FSS if they wish to receive reimbursement for their drugs under the Medicaid program. Because Medicaid accounts for almost 10 percent of domestic pharmaceutical sales, a manufacturer could lose substantial revenues if it did not have access to this segment of the market.[13] Also, because sales under the FSS represent only a small segment of the domestic pharmaceutical market, overall revenues are not greatly affected by offering these prices to federal customers. Furthermore, being on the FSS is significant to manufacturers because it enhances the likelihood that their products will be used in VA hospitals, where many of the nations' physicians receive part of their medical training.[14]

FSS prices are based on the prices that drug manufacturers charge their "most-favored" private customers. Specifically, under General Services Administration (GSA) procurement regulations, the FSS price is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.[15] To help VA determine the most-favored customer price, manufacturers are required to provide VA information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices. GSA regulations recognize that because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable, and (2) awarding the contract is otherwise in the best interest of the government.

VA and several other purchasers may actually pay a lower price than the listed FSS price for many drugs, under a provision of the Veterans Health Care Act of 1992.[16] Specifically, in exchange for having their drugs covered by Medicaid, manu-

[12] According to IMS America, a private vendor of pharmaceutical information, in 1999 the U.S. pharmaceutical market totaled about $142.4 billion in sales, including sales to federal and nonfederal entities.

[13] According to HCFA, Medicaid payments minus rebates for prescription drugs for fiscal year 1999 totaled about $13.7 billion. This figure may slightly overstate the actual market represented by Medicaid sales because Medicaid payments to pharmacies may be greater than the actual amounts pharmacies pay for drugs.

[14] For further discussion of the FSS and how FSS prices are determined, see *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain* (GAO/HEHS–97–60, June 11, 1997).

[15] See 48 C.F.R. sec. 538.270.

[16] See P.L. 102–585, sec. 603, codified at 38 U.S.C., sec. 8126. The provision covers innovator multiple-source drugs, insulin, and biological products such as vaccines and antitoxins. The provision does not cover noninnovator multiple-source or generic drugs.

facturers must sell their brand-name drugs on the FSS to four federal purchasers—VA, DOD, PHS, and the Coast Guard—at a price that is no higher than 76 percent of the nonfederal average manufacturer price, known as the "federal ceiling price" or FCP. The FSS price for these drugs for other federal purchasers may be higher than this ceiling.

Most drug products covered under the Veterans Health Care Act have FSS prices that are slightly above their FCP. As of February 2000, the FSS prices for products covered under the act were, on average, almost 8 percent above the FCR About 63 percent of the almost 6,300 products covered under the act[17] had FSS prices that were above the FCP.[18] For these products, the four purchasers protected under the act would pay only the FCP. About 14 percent of the products covered under the act had FSS prices equal to the FCP, and 23 percent had FSS prices that were below the FCP. When the FSS price was lower than the ceiling, it averaged almost 6 percent below the FCP.

FSS prices can also be well below the average wholesale prices that manufacturers suggest wholesalers charge retail pharmacies.[19] Recent FSS prices for 10 drugs commonly prescribed for the elderly were considerably lower than AWP (see table 2).

Table 2: Prices for Select Prescription Drugs Commonly Used by the Elderly, February 2000

Brand-name drug	Therapeutic category	AWP[a] (dollars)	FSS[b] (dollars)	Difference between AWP and FSS prices (percentage)
Lanoxin	Cardiac glycoside	$20.51	$10.05	51
Norvasc	Calcium channel blocker (high blood pressure)	122.86	61.27	50
K-Dur 20	Potassium replacement	49.98	23.73	53
Lipitor	Cholesterol-lowering	169.08	102.28	40
Lanoxin (different strength).	Cardiac glycoside	20.51	10.20	50
Prilosec	Gastrointestinal	119.57	58.73	51
Pepcid	Gastrointestinal	53.13	18.39	65
Glucophage	Oral antidiabetic	64.62	30.60	53
Fosamax	Osteoporosis	60.89	33.74	45
Synthroid	Thyroid	30.84	20.91	32

Note: These are the 10 most frequently prescribed drugs in the Pennsylvania Pharmaceutical Assistance Contract for the Elderly in 1999 Several of these drugs have generic versions.

[a] Medical Economics Company, ***Red Book February 2000 Update,*** vol. 19, no. 2 (Feb. 2000).
[b] Department of Veterans Affairs, Pharmacy Benefits Management Strategic Healthcare Group, http://www.vapbm.org (cited Feb. 14, 2000).

Prices Related to Medicaid Rebates

Many entities that receive federal assistance also obtain significant drug discounts through federal laws. The most notable are state Medicaid programs, which receive discounts in the form of rebates. Under OBRA, as amended, drug manufacturers must provide all state Medicaid programs a rebate on outpatient prescription drugs in order to have them covered by Medicaid.[20] For all brand-name products, the rebate is the greater of either 15.1 percent of AMP, or 100 percent of the difference between the AMP and the manufacturer's best price. The best price is essentially the lowest price offered any domestic purchaser other than state Medicaid programs.[21] Rebates for generic and over-the-counter drugs must be at least 11 percent of AMP. To protect against substantial price increases, an additional rebate is re-

[17] As of February 14, 2000, the FSS included 17,464 drug products; 6,274 were covered under the Veterans Health Care Act and 11,190 were not covered. Noncovered products are generally generic drugs. VA estimates that about 70 percent of its drug expenditures for fiscal year 1999 were for drugs covered under the Act.

[18] About 69 percent of the covered drugs with FSS prices above the FCP had FSS prices that were only 1 percent or less above the ceiling.

[19] Because AWP reflects prices charged the retail level of trade, it is typically higher than average manufacturer prices—AMP and NFAMP—which are charged at the wholesale level.

[20] Rather than directly purchasing drugs, Medicaid reimburses pharmacies for drugs purchased by Medicaid beneficiaries. Based on a formula set by the state, pharmacies are reimbursed an amount to cover a drug product's ingredient cost, subject to HCFA upper limits, plus a dispensing fee.

[21] Some prices are excluded in the determination of best price, such as FSS prices, prices charged entities covered under the Veterans Health Care Act, prices to state pharmaceutical assistance programs, prices that are nominal in amount, and single-award contract prices charged any federal agency.

quired for a brand-name product if its AMP increases more than the consumer price index, a measure of overall inflation. During fiscal year 1991, state Medicaid programs paid about $ 5.4 billion to pharmacies for prescription drugs and received about $553 million in rebates from manufacturers. By fiscal year 1999, drug payments had reached about $17 billion, with rebates in excess of $3.3 billion.[22]

Since 1992, federal law has also required drug manufacturers to offer certain nonfederal entities access to outpatient drugs at discounted prices as a condition for Medicaid coverage of their outpatient drugs.[23] Specifically, under Section 340B of the Public Health Service Act,[24] manufacturers must provide covered entities such drugs at or below a price equal to AMP reduced by the applicable Medicaid rebate percentage.[25] Entities eligible for the price discount include hospitals that serve a disproportionate share of Medicaid recipients; community health centers; and health centers that serve migrant, homeless, public housing, and Native American populations.[26] A recent study estimates that, during fiscal year 1997, 1,075 entities purchased outpatient drugs at these discounts with a total net purchase amount between $893 million and $1.2 billion.[27]

VA Contract Prices

VA has been able to obtain prices even lower than FSS prices through national contracts with manufacturers for select drugs. VA has obtained such prices because it seeks competitive bids from manufacturers for products that are therapeutically equivalent within specific drug classes.[28] VA then contracts with those manufacturers whose products it believes provide the best value, based on both medical effectiveness and price, in exchange for including their products on VAs national formulary and committing to use the products throughout VAs health care system.[29] According to VA officials, the winning bids in most cases are the lowest prices offered. During fiscal year 1999, VA purchases under national contracts totaled about $361.3 million, or about 23 percent of its drug expenditures. By February 2000, VA had 60 national contracts covering about 500 products.[30] For the 308 products that had both a national contract price and an FSS price as of February 14, 2000, the national contract price was, on average, about 33 percent lower than the FSS price. Because national contract prices are lower than FSS prices, the price differences between national contract prices and AWP, in turn, can be quite large. For example, the national contract prices for three cholesterol-lowering drugs that are among the top 50 drug products most commonly used by the elderly were, respectively, 70, 72, and 88 percent lower than AWP.[31]

FEDERAL MANDATES COULD RAISE DRUG PRICES FOR VARIOUS PURCHASERS

Extending federal prices for outpatient prescription drugs to a large group of purchasers, such as Medicare beneficiaries, could lower the prices these purchasers pay,

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[22] Rebates in the earlier years of the rebate program were based on a different percentage of AMP. Also, according to HCFA officials, payments for fiscal year 1999 may be understated because states do not typically submit all payment data to HCFA by the end of the fiscal year.

[23] See Office of Drug Pricing, *The Drug Pricing Program Established by Section 340B of the Public Health Service Act: Information Document* (Washington, D.C., Feb. 1999). The Office of Drug Pricing (now called the Office of Pharmacy Affairs), which is within HRSAs Bureau of Primary Health Care, is responsible for administering the Section 340B program.

[24] As added by sec. 602 of the Veterans Health Care Act of 1992.

[25] The rebate percentage is the total per-unit Medicaid rebate during a calendar quarter divided by the AMP for the quarter. HRSXs Office of Drug Pricing indicates that the ceiling price does not exceed AMP minus 15.1 percent for brand-name drugs and 11 percent for generic and over-the-counter drugs. An additional rebate is required if any brand-name product's price exceeds the increase in the consumer price index for all items. In addition, covered entities must ensure that drugs are not double discounted—that is, that manufacturers do not pay a Medicaid rebate on drugs already sold to the entities at a discounted price under Section 340B.

[26] See P.L. 102–585, sec. 602.

[27] See *An Analysis of Purchases, Savings and Participation in the PHS Drug Pricing Program* (Mathematica Policy Research, Inc., Washington, D.C., Sep. 30, 1999).

[28] VA also negotiates what is known as "blanket purchase agreements" with many manufacturers to obtain prices that are lower than listed FSS prices if VA uses specific product amounts. These agreements differ from national committed-use contracts in that they are not competitively bid and most apply to specific VA purchasers, such as one or more VA hospitals. As of February 14, 2000, there were 52 blanket purchase agreements in effect.

[29] See *VA Health Care: VA? Management of Drugs on Its National Formulary* (GAO/HEHS–00–34, Dec. 14, 1999).

[30] The contracts cover both brand-name and generic products and include some joint contracts with DOD.

[31] For additional information on VA national contracting practices and prices, see *DOD and VA Health Care: Jointly Buying and Mailing Out Pharmaceuticals Could Save Millions of Dollars* (GAO/T–HEHS–00–121, May 25, 2000).

but could raise prices to federal and other purchasers. Drug manufacturers could respond to a mandate that they extend federal prices to a larger share of purchasers by adjusting their prices to others. The larger the group that would be newly entitled to receive a federal price, the greater the incentive for drug manufacturers to raise that price. The Medicaid rebate experience suggests how federal and nonfederal drug price discounts could change if Medicare beneficiaries had access to the same price discounts available to federal purchasers. Following enactment of the rebate program, discounts for outpatient drugs decreased significantly because manufacturers raised the prices they charged large private purchasers.

Potential Price Effects of Combining Market Segments

Drug manufacturers have traditionally sold the same product at different prices to distinct groups or segments of purchasers, such as HMOs, private insurers, hospitals, and retail pharmacies. Manufacturers can segment the market In this manner because the purchasers who receive the lower prices do not, in turn, resell these products to other purchasers. As long as the groups remain independent in this way, manufacturers can tailor the price charged each group. This helps to explain why customers without drug coverage, or cash-paying customers, typically face higher prices at a retail pharmacy than HMOs or other large private purchasers pay.

The prices that manufacturers establish for different groups depend on how price sensitive each group is-that is, the extent to which the group would change the amount of a product it buys if the price rises or falls. For example, HMOs are more price sensitive than retail pharmacies because HMOs exercise control over the particular products they purchase through the use of formularies and other mechanisms that influence physicians' prescribing practices. Conversely, retail pharmacies have limited ability to determine which drugs they must have available because physicians' prescribing practices are largely outside their influence. Retail pharmacies must, therefore, stock a wide range of drug products that meet the needs of all of their customers, regardless of changes in price for those products.

If manufacturers were required to provide their drug products to both retail pharmacies and HMOs at the same prices, these two market segments would no longer be independent. Manufacturers would have to decide whether to provide retail pharmacies the same prices they have typically provided HMOs, or raise their prices to HMOs to minimize the negative impact on their profits. To assess the potential impact on profits, manufacturers would need to assess how much of their revenue they would lose by charging retail pharmacies the lower HMO prices, versus any losses in sales due to raising the prices to HMOs and other large private purchasers. Manufacturers would recognize that raising prices to these large purchasers could result in decreased sales. Manufacturers would likely temper their price changes depending on how price sensitive large purchasers were. If large purchasers were very price sensitive, sharply restricting their purchases as prices rose, manufacturers might restrain their price increases. If large purchasers were less price sensitive, manufacturers could raise prices more while experiencing the loss of fewer sales. The net result of requiring that retail pharmacies and large purchasers pay the same prices would likely be higher prices for those who had previously benefited from lower prices and lower prices for those who had not.

Extending federal prices to a large group of purchasers, such as Medicare beneficiaries, could have similar pricing implications. Large groups of purchasers that pay very different prices based on their price sensitivity would be combined and manufacturers would be required to charge everyone in the enlarged combined group the same price. The magnitude of the price effects would depend considerably on which federal price was provided and the number of beneficiaries that would now purchase drugs at that federal price.[32] For example, if the FSS price were extended to Medicare beneficiaries, the market segments that included FSS purchasers and cash-paying retail Medicare customers would be combined. In this case, the federal price would be based on prices paid by manufacturers' most-favored customers, and the volume of sales at the FSS price would be significantly larger than at present. Depending on the number of Medicare beneficiaries that would purchase their drugs at FSS prices, sales at FSS prices could be between 6 and 20 times larger than the current level.[33] How much manufacturers might charge would vary by product, de-

[32] For further discussion of the potential effects of extending FSS prices to nonfederal purchasers, see GAO/HEHS–97–60 June 11, 1997).

[33] In 1996, Medicare beneficiaries with drug coverage spent an average of $769 on prescription drugs; beneficiaries without coverage spent an average of $463. If the approximate 12 million beneficiaries that lacked drug coverage had access to FSS prices and those prices were lower than the prices they would pay otherwise, it could increase the volume of drugs they would pur-

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pending considerably on whether there were competing products, as well as the price sensitivity of the manufacturers' other customers. However, for those products whose retail and most-favored customer prices were considerably different, manufacturers would have the incentive to charge a new price that would likely fall somewhere between the two to offset any reduction in revenues. In these cases, extending the FSS price to Medicare beneficiaries could result in important out-of-pocket savings, particularly for cash-paying beneficiaries.[34] However, it could also raise the prices paid by private and federal purchasers, as increases in the prices manufacturers charged their best customers would, in turn, increase FSS prices.

Medicaid Rebate Experience

Federal efforts to provide state Medicaid programs discounts on prescription drugs demonstrate the potential price effects of mandating a federal price or discount that, in effect, combines purchasers from different market segments. Before the Medicaid rebate program was enacted, state Medicaid programs were paying near-retail prices for outpatient drugs, although collectively they were the largest single purchaser of prescription drugs. OBRA required that manufacturers provide rebates to state Medicaid programs on outpatient drugs based on the lowest prices they charged other purchasers. After the rebate program's enactment, the discounts that large private purchasers, such as HMOs and hospitals, received for many outpatient drugs dropped substantially.[35] Within 2 years, we found that the average best-price discount for the drugs they purchased was no greater than 15.3 percent of AMP—about the mandated minimum rebate for Medicaid programs.[36] This was confirmed by a CBO analysis that concluded that manufacturers were much less willing to give steep discounts to large purchasers when they had to give the same discounts to Medicaid.[37]

SUMMARY

By using its purchasing power, principally derived from the large purchases covered by the Medicaid program, the federal government obtains significantly discounted prices for prescription drugs from drug manufacturers for both federal and select nonfederal entities. Extending federal prices to Medicare beneficiaries could result in their paying less for drugs. However, these lower prices could come with a trade-off-federal and nonfederal purchasers might pay more if drug manufacturers raise prices to them to offset revenue losses resulting from extending federal prices to Medicare beneficiaries. The extent to which prices would change would vary by drug and would depend on many factors, including the number of Medicare beneficiaries affected, whether a drug had competition, and the price sensitivity of private purchasers. The decrease in price discounts following enactment of the Medicaid rebate program demonstrated the potential effects of reducing manufacturers' ability to differentiate among purchasers and charge some purchasers higher prices than others.

AGENCY AND OTHER COMMENTS

We obtained comments on the draft report from VA officials associated with pharmaceutical purchasing and pharmacy benefit management, including the Executive Director and Chief Operating Officer of the National Acquisition Center and the

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chase. Therefore, if their drug spending at FSS prices increased to about the same amount as those with coverage, sales at FSS prices would be about $9.2 billion, or over six times greater than total FSS sales in fiscal year 1999. If all 39 million beneficiaries had access to FSS prices and spent an annual average of $769 on drugs, FSS sales would be about $30 billion or about 20 times greater than total FSS sales in fiscal year 1999. Based on data from the 1996 Medicare Current Beneficiary Survey. See J.A. Poisal and G.S. Chulis, "Medicare Beneficiaries And Drug Coverage," *Health Affairs* (Mar./Apr. 2000), p. 252.

[34] Other beneficiaries with drug coverage, such as those enrolled in Medicare HMOs, may already receive drugs at discounted prices.

[35] See *Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals* (GAO/HEHS–94–194FS, Aug. 5, 1994). Also, see *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions* (GAO/HRD–93–43, Jan. 15, 1993).

[36] This is average percentage that the best price was below the AMP The average best price discount decreased because the average best price increased faster than the AMP during the 2-year period.

[37] See *CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (Washington, D.C., Jan. 1996). CBO also noted that many FSS prices increased significantly, perhaps because FSS prices were initially considered with private-sector prices in calculating rebates. In 1992, in the Veterans Health Care Act, the Congress exempted all drug prices paid by federal entities from rebate calculations.

Chief Consultant for the Pharmacy Benefits Management Strategic Healthcare Group. We also obtained comments from two nationally known researchers on pharmaceutical pricing issues. The reviewers agreed with our findings and provided technical comments, which we have incorporated where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that point, we will send copies to interested congressional committees and Members and agency officials, and will make copies available to others on request. If you or your staffs have any questions about this report, please call me, or John Hansen. Others who made major contributions to this report include Joel Hamilton, Elsie Picyk, and George Bogart.

LAURA A. DUMMIT,
Associate Director, Health Financing and Public Health Issues.

Senator SPECTER. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Chairman ROCKEFELLER. Thank you, Senator Specter.

Senator Wellstone, in order of original appearance.

Senator WELLSTONE. Thank you. Senator Specter, before you leave, I must say, that was a powerful line of questioning. I appreciate that.

Senator SPECTER. Thank you. I am general counsel on the other side, Senator Wellstone. [Laughter.]

Senator WELLSTONE. Just a couple of figures here to give this some context. The average Fortune 500 industry in the United States returned 4.5 percent profits as a percentage of revenue. The pharmaceutical industry returned this past year 18.6 percent. The average Fortune 500 industry returned 3.3 percent profits as a percentage of their assets. The pharmaceutical industry returned 17 percent. The average Fortune 500 industry returned 14.6 percent profits as a percentage of shareholders' equity. The pharmaceutical industry returned 29.4 percent. That is why this last year Forbes magazine, I think, said that the pharmaceutical industry had a, quote, "Viagra" kind of year when it came to profits.

The reason I mention that is I do think that both sets of questions are very relevant. Let me ask you, Mr. Secretary, because Mr. Chairman, I almost think that part of the Secretary's testimony would be good for the Finance Committee. I really do.

Chairman ROCKEFELLER. Almost anything would help.

Senator WELLSTONE. Almost anything would help. [Laughter.]

You are on the committee. You said it, I didn't.

This whole Federal Supply Schedule, the global budget that you have got, how key is it in keeping the costs down?

Mr. PRINCIPI. I am sorry, sir?

Senator WELLSTONE. The VA participates in this Federal Supply Schedule for pharmaceuticals, which is the global budget you set up. I just want to ask you, how important do you view this as in keeping VA's costs down for the prescription drug benefits that you are able to provide for the veterans?

Mr. PRINCIPI. Oh, I think it is terribly important to keep the price down to negotiate these large-volume purchases and get them on the Federal Supply Schedule. Everyone benefits, not only VA, but I believe we do it for DoD, Indian Health Service, Public Health Service. So we are basically the authority, the agency that is the procurement agent for many, if not all, of the managed health care systems in the United States, including the Bureau of

Prisons. So I think—and that has resulted in lower prices to our systems.

Senator WELLSTONE. Yes. Well, I am not trying to be clever and I am not trying to get you into sort of the thick of all the fights, but the chairman has said, look, we are doing this hearing and part of it is because there is this relationship right now, which is you have got more people coming on from Medicare that are veterans that put a strain on this system because we don't have it as a part of Medicare, right?

But the other connection, I think, is the way you do this, and what Senator Specter was saying is, gee, if we just give this industry a blank check, they will fill in the amount. If there is no cost containment, it will never be, Mr. Chairman, probably economically sustainable or politically sustainable. There is going to have to be some cost containment. And I am not making you take that position, but I am saying that I frankly think you have a model here that works and I think that there is no reason why it wouldn't be good for Medicare. There is no reason why for 40 million people who represent a pretty significant bargaining unit there shouldn't be some agreement.

Just as Senator Specter said, or maybe Senator Rockefeller said this, the NIH, my gosh, the NIH does a ton of this research that helps these companies, and then they get the patents. Well, if these pharmaceutical companies, if they are going to get the patent, they ought to agree to charge the people in this country a reasonable price. The government is the one that did the research.

So I think that we are just talking about, in a way, something that is fiscally responsible, and I, for one, would like to make the argument that you provide a model for where we should be heading with Medicare. I really believe that.

One more thing—the light is yellow—the $2 to $7. I think what I heard you say in your testimony—I mean, obviously, it is not fun for you to make this recommendation. I mean, it is clear by facial expressions it is not what you want to do. In your testimony, and tell me if I am wrong, I thought you said you weren't sure how it would affect demand. Is that what you said? Or do you know, in terms of, especially as Senator Rockefeller was saying, on the low-income end. Do you have any sense as to what would happen here?

Mr. PRINCIPI. I think we will depress demand somewhat. I still believe that at a $7 copayment for a 30-day prescription, we are still the most generous plan anywhere.

Senator WELLSTONE. Absolutely.

Mr. PRINCIPI. Again, with some plans, of course, you have an enrollment fee and you have deductibles and you might have a $5 copayment. But with ours, you don't pay any of the others and it is just a straight $7 copayment.

We are always concerned about copayments. We want to make sure that veterans who need the drugs can get them, but we feel confident, very confident that with a $7 copayment—veterans will be able to obtain the drugs they need. Of course, service-connected veterans are not included.

Senator WELLSTONE. Right, and this is another reason why I would love to have you before the Finance Committee. You are struggling with this. Senator Rockefeller has been the one that is

the leader. I have seen some of his quotes in the papers. We are talking about still a pretty significantly high premium, a 50-percent copay, and yet not even doing that well on the catastrophic expenses, and there are a lot of people who aren't going to participate. Here, the Secretary is in anguish over $2 to $7, and the Finance Committee might want to express a little bit more anguish over where they are heading.

Chairman ROCKEFELLER. No, we are anguishing, Senator Wellstone. [Laughter.]

Senator WELLSTONE. You are.

Chairman ROCKEFELLER. We are just not progressing.

Senator WELLSTONE. You might want to anguish and then progress.

Chairman ROCKEFELLER. That is a logical followup statement. And it is interesting, because you indicate the $2 to $7. We are working off the Breaux-Frist bill on one hand and the Gramm, what I call the Gramm-Rockefeller bill on the other hand, and if you take $318 billion under the Gramm bill, which we can't afford, the budget resolution doesn't allow for it, we have to go with a $52 premium, and obviously that won't stand. That is sticker shock and will never happen in this country. So you then have to pay down that money in order to lower the amount of the premium. As you do that, you are already taking a slim amount of drug benefit money and having to push that down further.

So the point that Senator Wellstone makes, that the $7 compared to the——

Mr. PRINCIPI. And if I could just add, before the Senator leaves——

Senator WELLSTONE. Yes, and I apologize.

Mr. PRINCIPI [continuing]. Is the fact that we have put a cap on of $840.

Chairman ROCKEFELLER. Right.

Mr. PRINCIPI. So if you are category two through six, $840 is the most you will ever have to pay in a year. The category sevens, we did not put a cap on. So category one is no copay at all. Two through six, only up to $840 a year.

Senator WELLSTONE. You are so far ahead of where most are.

Chairman ROCKEFELLER. Senator Nelson, and I want to say to Senator Craig, I well understand that you are here, thank you for coming, sir.

Senator CRAIG. No, go right ahead. I just came to listen for a while.

Chairman ROCKEFELLER. Do you want to say a word?

Senator CRAIG. No.

Chairman ROCKEFELLER. OK. Senator Nelson, I apologize to you.

Senator NELSON. Thank you, Mr. Chairman.

As you are looking at your pharmaceutical program and providing the prescription drug benefits for the retirees, military retirees, as you look at that and you say that you are 3 percent of the pharmaceutical market, is that what I think I heard you say?

Mr. OGDEN. Approximately.

Senator NELSON. And you don't believe that the cost containment that you have been able to achieve to date could be extended mathematically or pro rata wise across as you try to effect some of the

other 97 percent that wouldn't be included if we were trying to put together a purchasing group, if you will, or a contracting group to get a better price, is that because the cost containment you have achieved is probably a cost shift to the other 97 percent?

Mr. OGDEN. No——

Senator NELSON. Not that I am being critical of that. I don't mean to be critical.

Mr. OGDEN. No. In fact, my comment to that is, we represent 3 percent of the U.S. market and the efforts that we have effected and the pricing that we have received reflects that 3 percent of the U.S. market. If Medicare, for example, is 40 percent, just hypothetically, and you had States form consortiums and negotiate with the industry just like we negotiate with the industry, one would expect that you would see lower prices than we receive because the market share that would be in Medicare is much, much larger than what is in VA and DoD.

So my comment was, my personal opinion is, I don't favor linking Medicare to VA and the rest of the DoD and Coast Guard, et cetera. I believe that in the Medicare program, through the use of consortiums and through the use of strategies such as we have employed in the context of managing drug utilization, that Medicare could, in fact, drive market share and receive excellent pricing, but it would require the kinds of actions that we have taken as opposed to just linking Medicare to current VA pricing. That was my comment.

Senator NELSON. I think I now understand the distinction you were making. But wouldn't you be fearful if the 40-pound player versus a 3-pound player is now negotiating, that you wouldn't see a cost shift back to the VA and DoD?

Mr. OGDEN. It is possible.

Senator NELSON. Because every time you press it down here, it comes up over here——

Mr. OGDEN. That is a very real possibility.

Senator NELSON [continuing]. As long as the profits are going to continue to be at the level that they are right now, assuming that those would continue in the future. So it isn't as simple as we all would like to make it necessarily, but your experience, and you are to be congratulated, in my opinion, for what you have done for cost containment to try to bring down the costs to a rational level.

You are in an insurance business and you have figured out a way to make it work by controlling the costs, because otherwise you are chasing rising costs and you will never get there. You will never catch up. Your expenses will either be driven up, or if you are in the business of charging a premium, as I think we will be with respect to Medicare, the premium will just continue to rise as you chase those rising prices.

Mr. PRINCIPI. I think the fact is, we have a national problem in pharmaceutical costs. We have been talking today about Medicare, VA, DoD, and that we need to simply work together. The VA can't work in isolation. We need to work collaboratively with HHS and with DoD and the other health care providers. To the degree that we have learned some tough lessons and have applied them well and those lessons can be exported to other health care systems like

HHS, then so be it. To the degree we can cooperate, we need to explore that.

I don't want to see our costs go up, but I think we have a responsibility to address the national issues and the VA should be a player there.

Senator NELSON. Indeed, Mr. Secretary, I think you need to be a player there, because as the other players play, you want to be a participant so that it doesn't shift your direction. In other words, it is going to be important that all the players be in the room to avoid having what could otherwise happen. The smaller percentage could end up carrying a larger share of the load as a shift.

What we need to do is to find a way to achieve this without any significant cost shift to the American market. Now, maybe it will do something to the international market, but not to the U.S. market.

I appreciate it very much, and you are to be, once again, congratulated. Perhaps the 3-percent will show the 40 percent the way, and I thank you very much.

Mr. PRINCIPI. Thank you, sir.

Senator NELSON. Thank you, Mr. Chairman.

Chairman ROCKEFELLER. Thank you, Senator Nelson.

Let me just conclude this panel with my thanks to each and every one of you. It is, as you say, an overwhelming problem and an overwhelmingly complex one. It is stunning in the three or four or five times a week meetings that we have, and the meetings are just among Senate Republicans and Democrats on the Finance Committee, just getting into formularies and PBM's and private options and all the rest of it, it is mind-bogglingly complex.

But what comes up at the end of the day is the fact that the total amount of money that we have to spend on all of this, which includes, incidentally, Medicare reform, is $300 billion. That is what is in the budget resolution. There arises the very real question, which, in fact, reflects on the future of the VA and how we are going to be burdened, so to speak, by those flocking to us. There is potentially an argument to be made that if you take, let us say, according to the current thinking, about $10 billion over 10 years for Medicare reform out of the $300 billion, then you have $290 billion left over 10 years for prescription drugs.

Granted, nobody in the non-VA world has prescription drugs at this point, that is, unless they are getting it under an employer's plan, but there is a real case to made that $290 billion isn't going to do it. It is not going to be enough. So you have to either put on a premium, which is absolutely unsustainable politically and could never move in this place politically, or you have to cut it to the point where the drug money is insufficient. Drugs are going up, as has been pointed out.

I don't think you can do that to the American people. I don't think you can give them about a two-thirds drug benefit when their expectations are we are going to do it—and everybody ran on the idea we are going to do a prescription drug benefit. And if we don't, and there is that chance because agreement is so hard to reach, that is just going to increase the pressure on the VA, which I don't want to see, and neither do you.

So we thank all of you gentlemen very, very much and appreciate your courtesy in being here. Thank you, Mr. Secretary.

The second panel consists of Cynthia Bascetta, who is Director of Health Care for the Veterans' Health and Benefits Issues, U.S. General Accounting Office. If we could have some order in the room, I would appreciate it very much. She is accompanied by Walter Gembacz, who is the Assistant Director, Veterans' Health Care Issues. Also testifying will be Dr. Roger Herdman, who is Director of the National Cancer Policy Board, Institute of Medicine, and Dr. Michael Miller, who is a consultant to the Pharmaceutical Research and Manufacturers Association, PhRMA.

We welcome all of you. I am going to ask Cynthia Bascetta to begin, but I am going to interrupt you in about 2½ minutes for a special purpose, but you go ahead.

STATEMENT OF CYNTHIA A. BASCETTA, DIRECTOR, HEALTH CARE, VETERANS' HEALTH CARE AND BENEFITS ISSUES, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY WALTER GEMBACZ, ASSISTANT DIRECTOR, VETERANS' HEALTH CARE ISSUES

Ms. BASCETTA. Mr. Chairman and members, thank you for asking us to discuss our work conducted at your request on VA's management and oversight of its national formulary. VA's national formulary is designed to improve the quality of care for veterans as well as better manage its rapidly escalating costs for pharmaceuticals, which as we all know is typical of the entire health care industry.

My testimony is based on our review of formulary policies and practices in headquarters and VA's 22 networks, analysis of nationwide prescription data, three site visits, and our survey of 2,000 prescribers. In addition, we have included current information on the status of VA's actions to implement the recommendations we made this January.

As we reported earlier this year, VA has made significant progress establishing its national formulary. Specifically, about 90 percent of outpatient prescriptions were for national formulary drugs. Moreover, both prescribers and veterans generally report having access to the drugs they need.

Today, however, I would like to focus on our conclusion that VA needs to improve its oversight to fully achieve its standardization goal and to correct weaknesses in the waiver process for obtaining non-formulary drugs.

My first point is that VA has not fully achieved its goal of a standardized drug benefit, that is, that veterans should have access to the same drugs regardless of which medical center they visit. Noncompliance with VA's formulary directive, as well as VA's own policy allowing the networks flexibility to meet local needs with appropriate oversight, have impeded VA's progress.

Regarding compliance, we found that two of the three medical centers we visited in the spring of 2000 omitted national formulary drugs. One omitted 25 percent. The other omitted 13 percent. Together, nearly 450 drugs for high blood pressure, mental disorders, women's medical needs, cancer treatment, and digestive disorders were not available as formulary choices. As a result, physicians at

these two medical centers had to obtain approval to write over 22,000 prescriptions for drugs that should have been available without question. This wasted valuable clinical time and delayed patient treatment.

Chairman ROCKEFELLER. Ms. Bascetta, I am going to interrupt you at this time because I want all of us to pause for a moment. It was at precisely this minute 3 years ago that Officer Jacob Chestnut and Detective John Gibson of the U.S. Capitol Police were killed in the line of duty while trying to stop an intruder, so I think it would be appropriate for us to pay our respects in a moment of silence.

[A moment of silence was observed.]

Chairman ROCKEFELLER. Thank you. Please proceed.

Ms. BASCETTA. Thank you. Regarding flexibility to supplement the national formulary locally, we found that VA lacked criteria for determining the appropriateness of the network's actions when adding drugs. As a result, the flexibility given to the networks, while critical to ensuring that the health care needs of all veterans are met, could erode standardization if not closely managed.

During our review, all 22 networks added drugs not found on the national formulary, and they ranged from as few as five in one network to as many as 63 in another. In all, the networks added nearly 250 unique drugs.

My second point is that VA also needs better oversight of access to non-formulary drugs. VA policy requires that each network implement a process for obtaining drugs for veterans whose needs cannot be met by the formulary. In addition, networks are required to track both approvals and denials of non-formulary drugs.However, we found weaknesses in their approval processes. For example, although 40 percent of prescribers we surveyed reported being able to obtain approvals in a few hours, or even minutes, the other 60 percent reported much longer times, an average of 9 days. Prescribers were almost equally divided in their views on the ease or difficulty of obtaining non-formulary drugs. About 32 percent said it was difficult, while 29 percent said it was easy. Most important, however, 15 of the 22 networks had not complied with national policy to track non-formulary requests. Twelve had tracked neither approvals nor denials, and three tracked only approvals. Consequently, VA does not know if its approved requests meet VA's national criteria or if denied requests are appropriate.

Mr. Chairman, VA concurred with our conclusions and the recommendations we made to better achieve its standardization goal and to strengthen its oversight of the non-formulary process. While it is too early to tell how successful implementation will be, we are encouraged by the steps VA has taken and plans to take to implement our recommendations. We urge VA to issue its revised formulary directive, which is a significant improvement over current policy, as quickly as possible and to follow through with continuous oversight to ensure that veterans receive the pharmacy benefit in a well-managed manner.

This concludes my remarks and I would be happy to answer any questions that you might have.

Chairman ROCKEFELLER. Thank you very much, indeed.

[The prepared statement of Ms. Bascetta follows:]

PREPARED STATEMENT OF CYNTHIA A. BASCETTA, DIRECTOR, HEALTH CARE, VETERANS' HEALTH CARE AND BENEFITS ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss the Department of Veterans Affairs (VA) management and oversight of its national drug formulary. VA's national formulary is intended, in part, to control costs and better ensure that veterans have access to the same drugs regardless of which VA medical center they visit. VA medical centers were directed to make all national formulary drugs available to prescribers health care providers who have VA prescription-writing privileges.[1] To meet local patient needs, VA allows its 22 networks to add drugs to supplement the national formulary.[2] VA also requires each network to establish an approval process for obtaining drugs not listed in its formulary.

My testimony addresses problems we identified in two recent reports regarding implementation and standardization of the formulary and the approval process for nonformulary drugs at each network.[3] In conducting our work, we reviewed the formulary policies and activities of VA's headquarters and its 22 networks, analyzed nationwide VA prescription data, conducted site visits and interviewed VA officials at three medical centers located in three different networks, and surveyed 2,000 prescribers. We also updated this statement to reflect VA's most recent actions to implement our recommendations for improving its management and oversight.

In summary, while VA has made significant progress establishing a national formulary that has generally met with prescribers' and patients' acceptance, VA's oversight has not been sufficient to fully ensure standardization of its drug benefit nationwide. In our January 2001 report, we found that the three medical centers we visited were not in compliance with the national formulary. Specifically, two of three medical centers omitted more than 140 required national formulary drugs, and all three facilities inappropriately modified the national formulary list of required drugs for certain drug classes by adding or omitting some drugs. In addition, as VA policy allows, VISNs added drugs to supplement the national formulary ranging from 5 drugs at one VISN to 63 drugs at another. However, VA lacked criteria for determining the appropriateness of the actions networks took to add these drugs.

In addition to problems standardizing the national formulary, we identified weaknesses in the nonformulary approval process. While the national formulary directive requires certain criteria for approving nonformulary drugs, it does not prescribe a specific nonformulary approval process. As a result, the processes health care providers must follow to obtain nonformulary drugs differ among VA facilities regarding how requests are made, who receives them, who approves them, and how long it takes to obtain approval. We found that the length of time to approve nonformulary drugs averages 9 days, but can be as short as a few minutes in some medical centers. In addition, some VISNs have not established processes to collect and analyze data on nonformulary requests. As a result, VA does not know if approved requests meet its established criteria or if denied requests are appropriate.

In our January 2001 report, we made several recommendations to VA to improve its management and oversight of its national formulary. VA concurred with all of our recommendations and has taken, or plans to take, steps to implement them. Although these are clearly steps in the right direction, it is too early to tell how successful VA will be in establishing the continuous oversight needed to improve formulary management.

BACKGROUND

In fiscal year 2000, VA's pharmacy benefit provided approximately 86 million prescriptions at a cost of approximately $2 billion or about 12 percent of VA's total health care budget, compared to 6 percent of VA's total health care budget a decade ago. VA provides outpatient pharmacy services free to veterans receiving medications for treatment of service-connected conditions and to low-income veterans.

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[1] Veterans Health Administration's Directive 97–047, *VA National Formulary Directive,* Oct. 16, 1997.

[2] In 1995, VA began transforming its delivery and management of health care to expand access to care and increase efficiency. VA decentralize decisionmaking and budgeting authority to 22 regional Veterans Integrated Service Networks (VISN), which became responsible for managing all VA health care.

[3] *VA Health Care: VA's Management of Drugs on Its National Formulary* (GAO/HEHS–00–34, Dec. 14, 1999) and *VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs* (GAO–01–183, Jan. 29, 2001).

Other veterans who have prescriptions filled by VA may be charged a copayment for each 30-day supply of medication.[4]

Like many health care organizations, VA uses several measures in an effort to improve quality of care and control pharmacy costs. These include (1) implementing a national formulary, which standardizes the list of drugs available; (2) developing clinical guidelines for prescribing drugs; and (3) using compliance programs, such as prior authorization, to encourage or require physicians to prescribe formulary drugs.

VA medical centers individually began using formularies as early as 1955 to manage their pharmacy inventories. However, it was not until 40 years later in September 1995, that VA established a centralized group to manage its pharmacy benefit nationwide. In November 1995, when VISNs were established, VA's Under Secretary for Health directed each VISN to develop and implement a VISN-wide formulary. To develop their formularies, the VISNs generally combined existing medical center formularies and eliminated rarely prescribed drugs. In 1996, VA was required to improve veterans' access to care regardless of the region of the United States in which they live. As part of its response, VA implemented a national drug formulary on June 1, 1997, by combining the core set of drugs common to the newly developed VISN formularies. VA's formulary meets the Joint Commission for the Accreditation of Health Care Organizations' requirements for developing and maintaining an appropriate selection of medications for prescribers to use in treating their patient populations.

VA's formulary lists more than 1,100 unique drugs in 254 drug classes groups of drugs similar in chemistry, method of action, or purpose of use. After performing reviews of drug classes representing the highest costs and volume of prescriptions, VA decided that some drugs in 4 of its 254 drug classes were therapeutically interchangeable that is, essentially equivalent in terms of efficacy, safety, and outcomes. This determination allowed VA to select one or more of these drugs for its formulary so that it could seek better prices through competitively bid committed-use contracts.[5] Other therapeutically equivalent drugs in these classes were then excluded from the formulary. These four classes are known as "closed" classes. VA has not made clinical decisions regarding therapeutic interchange in the remaining 250 drug classes, and it does not limit the number of drugs that can be added to these classes. These are known as "open" classes.

To manage its pharmacy benefit nationwide, VA established the Pharmacy Benefits Management Strategic Healthcare Group (PBM). PBM is responsible for managing the national formulary list, maintaining databases that reflect drug use, and monitoring the use of certain drugs. PBM also facilitates the addition and deletion of drugs on the national formulary on the basis of safety and efficacy data, determines which drugs are therapeutically interchangeable in order to purchase drugs through competitive bidding, and develops safeguards to protect veterans from the inappropriate use of certain drugs. VISN directors are responsible for implementing and monitoring compliance with the national formulary and ensuring that a nonformulary drug approval process is functioning at each of their medical centers. Although VISN and medical center directors are held accountable in annual performance agreements for meeting certain national and local goals, attaining formulary goals has not been part of their performance standards.

NATIONAL FORMULARY STANDARDIZATION NOT YET ACHIEVED

While VA has made significant progress in establishing a national formulary, its oversight has not been sufficient to ensure that it is fully achieving its national formulary goal of standardizing its drug benefit nationwide. In our January 2001 report, we found three factors that have impeded formulary standardization: (1) medical centers we visited omitted some national formulary drugs from their local formularies, (2) VISNs varied in the number of drugs they added to local formularies to supplement the national formulary without appropriate oversight, and (3) medical centers inappropriately added or deleted drugs in closed classes.

[4] Section 201 of the Veterans Millennium Health Care and Benefits Act (P.L. 106–117) authorized the Secretary of the Department of Veterans Affairs to prescribe regulations to increase the copayment for each 30-day supply of medication for outpatient treatment of non-service-connected disabilities or conditions and to establish maximum monthly and maximum annual pharmaceutical copayments for veterans who have multiple outpatient prescriptions. In response, the Secretary has proposed regulations that, among other things, increases the copayment from $2 to $7. (Fed. Reg., Vol. 66, No. 136, July 16, 2001, pp. 36960–63.)

[5] Under committed-use contracts, VA commits to using primarily the contract drug, instead of other therapeutically interchangeable drugs, to guarantee drug companies a high volume of use in exchange for lower prices.

Nevertheless, most prescribed drugs were on the national formulary, and prescribers and patients were generally satisfied with the national formulary.

The first factor impeding standardization is that medical centers omitted some national formulary drugs from their local formularies. Almost 3 years after VA facilities were directed to make all national formulary drugs available locally, two of the three medical centers we visited in spring of 2000 omitted required drugs from the formularies used by their prescribers. At one medical center, about 25 percent (286 drugs) of the national formulary drugs were not available as formulary choices. These included drugs used to treat high blood pressure, mental disorders, and women's medical needs. At the second medical center, about 13 percent (147 drugs) of the national formulary drugs were omitted, including drugs used to treat certain types of cancer and others used to treat stomach conditions.

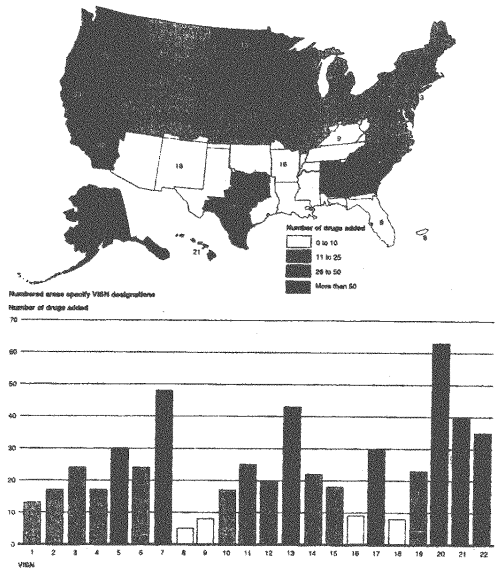
From October 1999 through March 2000, health care providers at these two medical centers had to obtain nonformulary drug approvals for over 22,000 prescriptions for drugs that should have been available without question because they are on the national formulary. Our analysis showed that at the first center, over 14,000 prescriptions were filled as nonformulary drugs for 91 drugs that should have been on the formulary.[6] At the other medical center, over 8,000 prescriptions for 23 national formulary drugs were filled as nonformulary drugs. If the national formulary had been properly implemented at these medical centers, prescribers would not have had to use extra time to request and obtain nonformulary drug approvals for these drugs, and patients could have started treatment earlier.

The second factor impeding standardization is the wide variation in the number of drugs added by VISNs to their local formularies. VA's policy allowing VISNs to supplement the national formulary locally has the potential for conflicting with VA's goal of achieving standardization if it is not closely managed. From June 1997 through March 2000, the 22 VISNs added a total of 244 unique drugs to supplement the list of drugs on the national formulary. As figure 1 shows, the number of drugs added by each VISN varies widely, ranging from as many as 63 to as few as 5. Adding drugs to supplement the national formulary is intended to allow VISNs to be responsive to the unique needs of their patients and to allow quicker formulary designation of new drugs approved by the Food and Drug Administration (FDA).[7] VA officials have acknowledged that this variation affects standardization and told us they plan to address it. For example, PBM plans to more quickly review new drugs when approved by FDA to determine if they should be added to the national formulary.

[6] After our visit, we were informed by a pharmacy official that the medical center adopted the national formulary as its own on June 30, 2000.

[7] VA national formulary policy provides that a new drug must be on the market for a minimum of 1 year before it can be added to the national formulary.

Figure 1: Variation in Number of Unique Drugs VISNs Added to Supplement VA's National Formulary, June 1997–March 2000



Source: GAO analysis of PBM data.

The third factor is that medical centers we visited inappropriately modified the national formulary list of drugs in the closed classes. Contrary to VA formulary policy, two of three medical centers added two different drugs to two of the four closed classes, and one facility did not make a drug in a closed class available. Moreover, the Institute of Medicine (IOM) found broad nonconformity at the VISN level.[8] Specifically, IOM reported that 16 of the 22 VISNs modified the list of national formulary drugs for the closed classes.[9] This also undermines VA's ability to achieve cost savings through its committed-use contracts.

While VA has not yet fully achieved national formulary standardization, most prescribed drugs were on the national formulary. From October 1999 through March 2000, 90 percent of VA outpatient prescriptions were written for national formulary drugs. The percentage of national formulary drug prescriptions filled by individual VISNs varied slightly, from 89 percent to 92 percent. We found wider variation among medical centers within VISNs 84 percent to 96 percent.

[8] In June 2000, IOM issued a report on the effect VA's national formulary has had on the cost and quality of VA health care, the restrictiveness of VA's national formulary, and how the national formulary compares with private and other government formularies. (IOM, *Description and Analysis of the VA National Formulary* [Washington, D.C.: IOM, June 2000].)

[9] IOM, *Description and Analysis of the VA National Formulary*, pp. 32–33.

Of the remaining 10 percent of prescriptions filled systemwide, VA's national database could not distinguish between nonformulary drugs and drugs added to local formularies by VISNs and medical centers to supplement the national formulary. VA's PBM and the IOM estimate that drugs added to supplement the national formulary probably account for about 7 percent of all prescriptions filled, and nonformulary drugs account for approximately 3 percent of all prescriptions filled. VA officials told us that they are modifying the database to enable them to identify which drugs are added to supplement the national formulary and which are nonformulary. This will allow them to better oversee the balance between local needs and national standardization.

Prescribers we surveyed reported they were generally satisfied with the national formulary. Seventy percent of VA prescribers in our survey reported that the formulary includes the drugs their patients need either to a "great extent" or to a "very great extent." Approximately 27 percent reported that the formulary meets their patients' needs to a "moderate extent," with 4 percent reporting that it meets their patients' needs to a lesser extent. No VA prescribers reported that the formulary meets their patients' needs to "very little or no extent." This is consistent with IOM's conclusion that the VA formulary "is not overly restrictive."

Veterans also appear satisfied with their ability to obtain the drugs they believe they need. At the VA medical centers we visited, patient advocates [10] told us that veterans made very few complaints concerning their prescriptions. In its analysis of patient complaints, IOM found that less than one-half of 1 percent of veterans' complaints were related to drug access.[11] IOM further reported that complaints involving specific identifiable drugs often involved drugs that are marketed directly to consumers, such as Viagra.[12] Our review also indicated that the few prescription complaints made were often related to veterans trying to obtain "lifestyle" drugs or refusals by VA physicians and pharmacists to fill prescriptions written by non-VA health care providers.[13] VA may fill prescriptions written by non-VA health care providers only under limited circumstances, for example, when the veteran is housebound and receives additional compensation because of a service-connected disability.[14]

APPROVAL PROCESSES FOR NONFORMULARY DRUGS HAVE WEAKNESSES

While the national formulary directive requires certain criteria for approval of nonformulary drugs, it does not prescribe a specific nonformulary approval process. As a result, the processes health care providers must follow to obtain nonformulary drugs differ among VA facilities regarding how requests are made, who receives them, who approves them, and how long it takes to obtain approval. In addition, some VISNs have not established processes to collect and analyze data on nonformulary requests. As a result, VA does not know if approved requests meet its established criteria or if denied requests are appropriate.

Both the people involved and the length of time to approve nonformulary drugs varied. The person who first receives a nonformulary drug approval request may not be the person who approves it. For example, 61 percent of prescribers reported that nonformulary drug requests must first be submitted to facility pharmacists, 14 percent said they must first be submitted to facility pharmacy and therapeutics (P&T) committees, and 8 percent said they must first be sent to service chiefs. In contrast, 31 percent of prescribers reported that facility pharmacists approve nonformulary drug requests, 26 percent said that facility P&T committees approve them, and 15 percent told us that facility chiefs of staff approve them. The remaining 28 percent reported that various other facility officials or members of the medical staff approve nonformulary drug requests. The time required to obtain approval for use of a nonformulary drug also varied depending on the local approval processes. The majority of prescribers we surveyed (60 percent) reported that it took an average of 9 days

[10] Patient advocates are VA employees who are responsible for receiving and acting on complaints from veterans.

[11] IOM obtained formulary-related complaints from a nationwide database of veteran complaints for over 90 percent of all VA facilities representing all 22 VISNs. IOM determined that only 2,385 of 570,937 veteran complaints were attributed to the national formulary. No VISN had significantly more complaints than any other. (IOM, *Description and Analysis of the VA National Formulary*, p. 145.)

[12] Viagra (sildenafil), which is used to treat erectile dysfunction, is available within VA only through the nonformulary drug approval process.

[13] We asked prescribers in our survey how often in 1999 their patients asked them to rewrite prescriptions from non-VA prescribers so that they could be filled by VA. Thirty-one percent said "often" or "very often," 34 percent reported that it occurred "occasionally," and 21 percent said "seldom." Fourteen percent said that they never received such requests.

[14] See 38 U.S.C. §1712(d); 38 C.F.R. §17.96, and Op. VA Gen. Coun. 41–91 (1991).

to obtain approval for use of nonformulary drugs.[15] But many prescribers also reported that it took only a few hours (18 percent) or minutes (22 percent) to obtain such approvals.

During our medical center visits, we observed that some medical center approval processes are less expeditious than others. For example, to obtain approval to use a nonformulary drug in one facility we visited, prescribers were required to submit a request in writing to the P&T committee for its review and approval. Because the P&T committee met only once a month, the final approval to use the requested drug was sometimes delayed as long as 30 days. The requesting prescriber, however, could write a prescription for an immediate 30-day supply if the medication need was urgent.

In contrast, another medical center we visited assigned a clinical pharmacist to work directly with health care providers to help with drug selection, establish dose levels, and facilitate the approval of nonformulary drugs. In that facility, clinical pharmacists were allowed to approve the use of nonformulary drugs. If a health care provider believed that a patient should be prescribed a nonformulary drug, the physician and pharmacist could consult at the point of care and make a final decision with virtually no delay.

Prescribers we surveyed were almost equally divided on the ease or difficulty of getting nonformulary drug requests approved. (See table 1.)

Table 1: Ease of Obtaining Nonformulary Drug Approvals Reported by Prescribers

Response categories	Percentage reporting
"Easy" or "very easy"	29
"About as easy as difficult"	40
"Difficult" or "very difficult"	32

Note: Percentages do not total 100 because of rounding.
Source: GAO survey.

Regardless of whether the nonformulary drug approval process was perceived as easy or difficult, the majority of prescribers told us that their requests were generally approved. According to our survey results, 65 percent of prescribers sought approval for nonformulary drugs in 1999. These prescribers reported that they made, on average, 25 such requests (the median was 10 requests). We estimated that 84 percent of all prescribers' nonformulary requests were approved.

When a nonformulary drug request was disapproved, 60 percent of prescribers reported that they switched to a formulary drug. However, more than one-quarter of the prescribers who had nonformulary drug requests disapproved resubmitted their requests with additional information.

For patients moving from one location to another, the majority of prescribers we surveyed told us that they were more likely to convert VA patients who were on a nonformulary drug obtained at another VA facility to a formulary drug than to request approval for the nonformulary drug. (See table 2.)

Table 2: Likelihood of Prescribers' Converting Patients From Nonformulary Drug Prescriptions to Formulary Drug Prescriptions

Response categories	Percentage reporting
"Likely to convert" or "very likely to convert"	64
"As likely to convert as to seek approval for the nonformulary drug"	18
"Likely to seek approval for the nonformulary drug" or "very likely to seek approval of nonformulary drug"	18

Source: GAO survey.

Contrary to the national formulary policy, not all VISNs have established a process for collecting and analyzing data on nonformulary requests at the VISN and local levels. Twelve of VA's 22 VISNs reported that they do not collect information on approved and denied nonformulary drug requests. Three VISNs reported that they collect information only on approved nonformulary drug requests, and seven reported that they collect information for both approved and denied requests. Such information could help VA officials to determine the extent to which nonformulary drugs are being requested and whether medical center processes for approving these

[15] In emergencies, exceptions are made to allow the patient to obtain the drug more quickly.

requests meet established criteria. In its report, IOM noted that inadequate documentation on such matters could diminish confidence in the nonformulary process.

PLANS FOR IMPROVING OVERSIGHT ARE PROGRESSING

We are encouraged by VA's actions, but it is too early to tell how successful it will be in addressing our recommendations for improving its management and oversight of the national formulary. To improve standardization of its formulary, we recommended that VA establish (1) a mechanism to ensure that VISN directors comply with VA's national formulary policy and (2) criteria that VISNs should use to determine the appropriateness of adding drugs to supplement the national formulary and monitor the VISNs' application of these criteria. VA's PBM has developed changes to its database that will provide comparative national data on VISN, nonformulary, and national formulary drug use. PBM also plans to share these data, including identification of outliers, with all 22 VISNs and coordinate with VISN formulary leaders to facilitate consistent compliance with national formulary policy. In addition, VA (1) drafted criteria for VISNs to use to determine the appropriateness of adding drugs to supplement the national formulary list, which it intends to include in a directive; (2) is developing a template for VISNs to document all VISN formulary additions; and (3) intends to review more quickly all new FDA-approved drugs for inclusion in the national formulary.

To improve its nonformulary drug approval process, we recommended that (1) VA establish a process to ensure timely and appropriate decisions by medical centers and (2) veterans be allowed continued access to previously approved nonformulary drugs, regardless of where they seek care in VA's health care system. In addressing these recommendations, VA plans to incorporate into its revised formulary directive the fundamental steps that all medical centers must take in establishing and reporting their nonformulary activities. VA also plans to include in its revised formulary directive a specific requirement that approved nonformulary medications will continue if a veteran changes his or her care to a different VA facility.

We also recommended that VA enforce existing requirements that VISNs collect and analyze the data needed to determine that nonformulary drug approval processes are implemented appropriately and effectively in their medical centers, including tracking both approved and denied requests. VA plans to establish steps for reporting its nonformulary approval activities. PBM has begun initial discussions with VA's Information Management Office about planning for the changes.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the Committee may have.

Chairman ROCKEFELLER. In fact, Dr. Herdman, I actually intended to call on you first, and I don't regret not calling on you first, but that was my intention, simply because you have the Institute of Medicine's report on these matters and I think it does make sense for you to give that overview, if you would be willing to do so, sir.

STATEMENT OF ROGER HERDMAN, M.D., DIRECTOR, NATIONAL CANCER POLICY BOARD, INSTITUTE OF MEDICINE

Dr. HERDMAN. Thank you, Mr. Chairman. The Institute is very happy that you asked us to come and brief you on our report, a copy of which I think you have, but I will leave some copies for you.

I am currently the Director of the National Cancer Policy Board, but as you know, Mr. Chairman, last year when we delivered our report to you and to the Veterans Administration, I was the director of that particular study. That study was ordered up by the Congress and paid for in its entirety by the VA and we were asked to look at four issues: The restrictiveness of the VA's national formulary, its effects on quality, its effects on cost, and a comparison of the national formulary with formularies in other private and public sector drug benefits.

In general, the IOM committee that performed this report supported the VA national formulary, but pointed out some problems and made some recommendations for corrections of problems. I

might say parenthetically that we were coordinating with the GAO insofar as their policies and procedures allow and that we are in general agreement with their findings.

The committee found that a formulary is the continually revised list of pharmaceuticals selected for patient care. The history of formularies goes back over 200 years in this country, and almost all Americans are now covered by formularies. VA began using formularies along with other U.S. hospitals and encouraged by the JCAHO about 50 years ago, so formularies are not new. They have been for decades standard features of organized health care systems.

The VA formulary is a list of about 1,200 drugs. It provides a uniform national entitlement, or intends to provide a uniform national entitlement to a selection of drugs reasonably comparable to that of other formularies and it restricts access to a small number of drug classes comprising about 15 percent of the dollar cost of the pharmacy benefit. That is, it is partially closed. By allowing choice among products and by its ability to influence market share in closed or preferred classes, the formulary allowed the health care system to present drug sellers with a price-sensitive demand and thereby to negotiate lower prices, and that is the point of the formulary.

The IOM committee did not find convincing high-quality scientific studies or other persuasive evidence that formularies in general, or the VA national formulary specifically, have deleterious effects on the quality of care unless they had arbitrary controls or benefit restrictions that excluded medically necessary drugs or had limits on prescriptions or caps on volume or the like. The VA national formulary does not have such features and drugs that are not listed in closed classes are available by a non-formulary exceptions process, although, as Ms. Bascetta has pointed out, there are problems with that process.

Specifically, the committee reviewed the elements of restrictiveness and those elements are listed in our report. I will summarize by just saying that we did not find that the VA's national formulary was overly restrictive, although as has been said here now several times, the non-formulary exceptions process was found to be inconsistent across the country without accurate reporting of results.

We reviewed changes in six classes before and after the national formulary, from January 1995 to July 31, 1999. The VA has estimated that about $572 million was saved over that time period from their contracting and acquisitions process. That includes items that are not part of the national formulary. We estimated that over a slightly shorter time period, conservatively, $100 million was saved. This did not include one closed class, blanket purchase agreements or other missing data, and that represents substantial saving.

With respect to quality, we reviewed a number of aspects of quality, primarily structural, and found that there was no noticeable effect on quality, although the data are not adequate to really make a strong case one way or the other.

So we made a number of recommendations and I am going to briefly enumerate them. We recommended that the VA not wait, as

they do now, or did then, for 1 year before considering new drugs approved by the FDA for addition to formularies. We recommended that the VA consider, as Ms. Bascetta has pointed out, the divergence of VISN, that is, regional and local formularies from each other and from the national formulary, and move toward more uniformity.

And we recommended that the VA construct a policy on therapeutic interchange, that is, substitution of formulary drugs for nonformulary drugs that are prescribed, and make one that does not subject veterans to frequent changes from one drug to another when contracting or formulary changes are made.

And we recommended in general that the formulary be continued and that the drugs in closed classes continue to be restricted and that the VA continue to negotiate prices, which they were doing, but that they collect better information, better data on their costs, patient-level data on inpatient, outpatient, and pharmacy costs, which would allow them to assess the impact on costs of the national formulary, and in particular to assess the impact of offsetting costs, shifting from various parts of the VA budget to other parts of the VA budget.

I apologize for being a little bit over time, Mr. Chairman, but that concludes my report and I would be happy to answer any questions.

Chairman ROCKEFELLER. No, don't apologize. We have this weird system here based upon the concept that, somehow, if we have red, yellow, and green lights, that we become efficient. [Laughter.]

I have never heard that word applied to either the Senate or any part in the Senate, so don't be embarrassed. But on the other hand, let me also say that all of your testimony is included in the record automatically, and the light is just a subtle reminder—we are thinking about having firecrackers and things go off, but we haven't reached that point yet.

[The prepared statement of Dr. Herdman follows:]

PREPARED STATEMENT OF ROGER HERDMAN, M.D., DIRECTOR, NATIONAL CANCER POLICY BOARD, INSTITUTE OF MEDICINE

INTRODUCTION

In June 2000 the Institute of Medicine's (IOM) VA Pharmacy Formulary Analysis Committee (the committee) delivered to the Department of Veterans Affairs (VA) and to House and Senate committees, including the Senate Committee on Veterans Affairs, a report on the VA National Formulary which had been requested in 1998 by the House Appropriations Committee in House Report 105–610. The report responded to four concerns outlined in the House Report: the restrictiveness of the formulary, its effect on quality of care of veterans, its effect on costs to the VA, and a comparison to other public- and private-sector formularies. Senator Rockefeller, then ranking minority member of the Senate Committee on Veterans Affairs, aware of and interested in the IOM study, also at about that time asked the U. S. General Accounting Office (GAO) to look at related issues with the VA formulary. The IOM and GAO coordinated efforts to comply with these congressional requests. The IOM also received substantial cooperation and information from the Veterans Health Administration (VHA), especially the Pharmacy Benefits Management Strategic Healthcare Group (PBM). The IOM work was funded exclusively under a contract with the VA. The IOM committee was made up of experts from the private sector with extensive expertise and experience in medicine, epidemiology, pharmacology, pharmacy, pharmacy benefits and formulary management, nursing, managed care, health economics, and representatives from the Disabled American Veterans and the Paralyzed Veterans of America.

Although individual veterans health facilities have used formularies beginning 40 to 50 years ago, only in 1997 was the VA National Formulary implemented. It is a list of about 1,200 generic, brand name, and over-the-counter drugs, devices, and supplies that provides the basis for a uniform national entitlement for all regions and facilities of the VHA, including 22 VISN (regional) and many local formularies. The formulary system consists of all measures that the VHA employs to manage the use of agents on its lists, including a non-formulary exceptions process, drug class reviews, the use of pharmacy and therapeutics (P&T) committees, and drug treatment guidelines. The National Formulary is partially closed, that is, some drug classes are closed or subject to restrictions, limiting choice to certain preferred of committed-use agents as a way of supporting VA negotiations for lower drug prices and meeting VHA market share objectives. Generic prescribing, generic substitution and therapeutic interchange (that is, substitution of a formulary for a non-formulary drug within a drug class) are also employed in managing the formulary system. Although minimal copayments have been imposed on some classes of veterans, to date they have not been available as a practical formulary management strategy.

FINDINGS

RESTRICTIVENESS: The IOM report first discussed whether the VA National Formulary was overly restrictive. According to the committee, if the formulary structure or formulary system controls deny or significantly delay access to drugs that, in the reasonable judgment of medical experts, are clinically indicated, then the VA formulary meets the definition of overly restrictive. Criteria of restrictiveness include: number of items on the formulary, number of closed classes, number of drugs in the closed classes, timeliness of addition of new drugs, responsiveness on the non-formulary exceptions process, sensitivity of therapeutic interchange policies to patient risks, OTC coverage, and generic substitution. Other limits might include: exclusion of drugs or drug classes, prescription quantity of number limits, high copayments, and prior approval policies, although these are often considered more in the nature of scope of benefit definitions. The committee found that, for the most part, the VA National Formulary compared well with formularies in the private or Medicaid sector. It was not overly restrictive, by informed medical judgment, in terms of overall coverage, conservative closure of classes and numbers of items in a closed class, OTC coverage, and generic substitution. Some problems were identified in non-formulary exceptions processes, therapeutic interchange, and timeliness of addition of newly FDA-approved drugs having to do with consistency across the VHA, national policies, and patient satisfaction, which will be referred to later under recommendations. The committee also reviewed what was known about physician and patient satisfaction related to the National Formulary as a possible indicator of restrictiveness. Although there was some evidence of dissatisfaction from VA complaint records and physician surveys, and although there were shortcomings in the quality of these data, in general they did not indicate high levels of specific complaints or dissatisfaction. The committee concluded that at the time the study was done, the VA National Formulary was not overly restrictive.

COSTS: With the help of economists from the Harvard Medical School Department of Health Care Policy, the committee next examined the effect of the VA National Formulary on the cost of drugs to the VHA. In economic terms, the objective of the VA National Formulary is to make the demand for specific prescription drugs more responsive to price than might otherwise have been the case. Formularies increase a buyer's bargaining power, enabling buyers to be more aggressive in price negotiation. By excluding certain products or by shifting demand significantly between competing products, the buyer presents a seller with a more elastic, or price-responsive, demand, thereby inducing a lower price. The greater the ability to direct the volume of prescriptions between competing products, the more elastic the demand and the greater the bargaining power of the buyer. Of course, the buyer must be careful not to exclude medically necessary drugs or implement interchanges that cause risks to patients.

As of February 2000, the VA claimed that the difference between actual expenditures on drugs and what would have been spent absent the National Formulary and other contracting activities from FY 1996 through FY 2000 amounted to over $572 million. The IOM used a more conservative approach, which counted only savings from favorable price negotiations multiplied by drug use in six closed or preferred classes and did not include blanket purchase agreements, generic purchases under contract, bulk buying, and savings from patent expirations, among others. The IOM method also compared pre-National Formulary prices with post-National Formulary prices over a more limited time (from the date of class closure to opening or end of data in July 1999). Estimated savings approximated $100 million over about the

first two years of the National Formulary, that is, about 3% of total pharmacy or 15% of the six closed and preferred class expenditures analyzed over that time period. The committee also explored changes in inpatient use associated with changes in the formulary. By the gross techniques used, no significant changes were observed. The committee concluded that the VA National Formulary was cost saving, probably generating savings of $100 million over two years and did not appear to have any effect on hospital admissions for selected heart- or ulcer-related conditions.

QUALITY: Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge. There are few data on anything except the structural characteristics of the VA National Formulary, and the committee found only very scanty data directly relating formulary elements to veterans' healthcare outcomes. Therefore, the committee looked predominantly at structural factors. These included clinical pharmacy services, local facility P&T committees, VISN formulary committees, the VA PBM and Medical Advisory Panel (MAP). The committee also examined the quality and availability of existing and newly FDA-approved drugs on the formulary, drug class reviews and therapeutic guidelines, the non-formulary process, therapeutic interchange policies, and drug utilization review. As noted earlier, the IOM noted no changes in hospital utilization as a result of the National Formulary, and existing (and often flawed) survey data did not persuasively indicate substantial levels of patient or physician dissatisfaction.

There is some evidence that VHA pharmacy services and the performance of pharmacists in clinical roles have been strengthened and improved, and although this has been to some extent independent of the National Formulary, it probably has had a beneficial effect on quality of care. It is uncertain whether the implementation of the National Formulary has diminished the role of local P&T committees which could effect quality of prescribing in local facilities. VISN level formulary committees appear in some cases to be dominated by pharmacists raising the question of whether they emphasize pharmacy budgetary issues over quality of pharmaceutical care. The committee assessed the performance of the VA PBM and MAP by examining the quality of the formulary and formulary system. In general, no serious problems that could affect quality were observed, although recommendations (described later) were made in the areas of therapeutic interchange, non-formulary exceptions, and additions of newly FDA-approved drugs, among others. These might indicate some quality problems. In the opinion of the IOM committee, VA drug class reviews and therapeutic guidelines were of high professional quality and likely to have a good effect on quality of care. Unfortunately, identification and tracking of adverse drug events, which could be important indicators of quality effects, are so spotty and incomplete that they are not useful.

The committee concluded that a completely firm and final answer to the question of quality would require scientifically sound evidence of formulary influences on quality of care that affect process of care and health outcomes of veterans, but there are no such epidemiological or other well-designed studies of the VHA. The absence of persuasive reports of substantial worsening of health outcomes in the medical literature attributable to a closed or partially closed formulary either for the VHA or for millions of covered lives in managed care (MCO) or private sector pharmacy benefit management organizations is not proof of no effect, although it is somewhat reassuring. Based on the available information and the committee's analysis, the committee concluded, therefore, that there is no reason to abandon the National Formulary and every reason to improve it.

COMPARISONS: Almost all MCOs offer pharmacy benefits and have formularies which are closed or partially closed. In general, these formularies employ prior approvals, exclusions, and copayments which were not part of the VA National Formulary at the time of the IOM study. They also may use generic substitution and therapeutic interchange (although almost always only with permission of the prescriber). Medicaid formularies vary from state to state. They tend to be inclusive as only limited exclusions are allowed by law if drug companies want their drugs included and agree to sign rebate agreements. However, prior approvals are common and various other limits, such as prescription limits on quantity or frequency, may be used which are not part of the VA National Formulary. The DOD benefit, formularies, and formulary systems were in transition at the time of the IOM study. The DOD Basic Core Formulary, mail order formulary, and multiple treatment facility formularies were not comparable to the VA National Formulary and formulary system.

In examining public and private sector formularies in comparison to the VHA, the committee concluded that some are more open, for example, Medicaid programs are required to offer all drugs on the Federal Supply Schedule that manufacturers list for rebates. Some are more restrictive. They require prior approvals and exclude

some drugs. All are variable, some probably more so than the VA. Some controls that were not part of the VA system at the time of the study, such as relatively costly deductibles and copayments, may present real barriers to needed drugs, especially for low-income patients. These controls are part of DOD requirements for some eligibles or employed by some managed care plans. Other controls, such as generic substitution and therapeutic interchange are in common use in many systems. Overall, the committee concluded that the National Formulary's effects on quality are likely comparable to those of formularies in private and other public-sector programs.

RECOMMENDATIONS

The IOM committee proposed nine recommendations.

With respect to VA use of a National Formulary, the committee recommended that the VA should continue to close classes prudently and to practice generic substitution and therapeutic interchange of branded drugs to meet its particular quality and price objectives.

With respect to management of the formulary, the VA should examine drugs newly approved by the FDA in a timely manner and abandon the fixed waiting period of one year before addition to the formulary. Drugs that provide significant improvement in treatment options should be given priority review.

The balance between standardization and systemwide uniformity and deference to local autonomy and preferences in the VA National Formulary should be recalibrated towards a more uniform national approach before divergence or inconsistencies in the formularies (which sometimes exceed 100 drugs) and formulary systems increase further.

Therapeutic interchange should be consistent in important practices and policies of notification and control. The VA should develop and implement a policy on the frequency and number of interchanges in long-term drug therapy that can result from formulary or contract changes.

Improvements in consistency and reporting of the non-formulary process should be made. The VHA should mount pilot tests of non-formulary exceptions processes that increase responsiveness and physician and patient acceptance.

The VHA should improve acceptance of the National Formulary by its stakeholders, including members of the health professionals and veterans, by, for example, representation in formulary discussions above the local P&T committee level, strengthened formulary committee participation by physicians, and a consistent policy of educating veterans about therapeutic interchanges and other formulary matters. Veteran consumers might be involved in input to the VHA, either in some advisory capacity, as is now required for the DOD Uniform Formulary, or as members of P&T or formulary committees.

The VHA needs better information on formulary system functions and their effects to ensure good management of the National Formulary. The VHA should mount studies that illuminate quality implications of the National Formulary. Congress should support the collection of data to improve National Formulary management and well-designed programs to inform formulary and drug treatment performance, quality, and cost.

With respect to effects on costs, the VHA should continue to make careful choices among drugs, based first on quality considerations, but with an understanding of cost implications, and should negotiate the best prices possible using the leverage of committed use and the ability to drive market share. The VHA should collect data to perform analyses addressing the question of offsetting expenditures and cost shifting.

CONCLUSION

In general, the IOM committee noted the extensive use of formularies in health care systems and supported specifically the VA National Formulary in concept and execution with some findings of problems and recommendations for needed improvements. At the conclusion of the study, the IOM provided some 100 copies of the report to the VA. The IOM committee met with the VA to explain the study and was led to believe then and subsequently that the VA was in agreement with many of the findings and recommendations and was moving forward with a process to implement changes consistent with the IOM report. The IOM has not monitored this process.

Chairman ROCKEFELLER. Dr. Miller, your presence here is very important and we welcome you, sir.

STATEMENT OF MICHAEL D. MILLER, M.D., CONSULTANT TO THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATION (PhRMA)

Dr. MILLER. Thank you, Mr. Chairman. I won't take your last statement to mean I can take 20 minutes.

Mr. Chairman, I am honored to be here today to discuss the VA's management of pharmaceuticals and the IOM's and GAO's studies on this issue. I am currently a health policy and communications analyst, educator, and consultant and I work on issues related to the quality of health care and the development of new medical treatments. I have spent considerable time in the past examining the VA's national formulary policies and am currently a consultant for PhRMA, but I want to make it clear the views I am expressing today are my own.

There are three key points I would like to make. First, the——

Chairman ROCKEFELLER. Now, I have got to understand this. You are here representing PhRMA, but your views represent your own views?

Dr. MILLER. I just want to make it clear that I am a consultant to PhRMA, in case somebody asks who my clients are.

Chairman ROCKEFELLER. A consultant to them, I see. OK.

Dr. MILLER. They are one of my major clients.

Chairman ROCKEFELLER. Then I apologize for my question.

Dr. MILLER. It is perfectly understandable.

There are three key points I would like to make. First, the quality of care received by America's veterans should be the focus for assessing the VA's pharmacy programs. Second, veterans receiving care from the VHA are different from patients receiving care from private managed care plans or Medicaid programs. And third, although the VHA's pharmacy practices are often compared to those used by private managed care plans or State Medicaid programs, the VA as a Federal agency is different and is forced to operate differently. I will expand upon each of these areas and conclude with some thoughts about future directions.

In discussing quality of health care, I prefer to focus in on the individual patient level. The VA's primer on outcomes states, "Outcomes measures help bring the focus of the entire health care delivery system back to the patient. Rigorous and continuous evaluation of the process of care through outcomes measurements analysis will ultimately improve the quality of care."

In addition, the document called "The Principles of a Sound Drug Formulary System," which was endorsed by the VA, "recognizes that patient care may be compromised if its formulary system is not optimally developed, organized, and administered." These statements taken together, form a good framework for thinking about VA's pharmaceutical policies.

The IOM and the GAO have each done a good job in analyzing the VA's pharmacy systems. I would like to highlight some of their findings and comment on some of the limitations of their studies and the data that was available to them.

As a component of outcomes measurement, the IOM found that hospitalizations for certain conditions did not change with the implementation of restrictions for medicines for these illnesses. However, the IOM's conclusions may be questioned, if it is believed, as

has been discussed earlier, that the VA is seeing more and more patients who are only using the VA for limited services, such as Medicare beneficiaries who might seek prescription drugs.

The IOM also found some problems with VA's therapeutic interchange practices, as Dr. Herdman just mentioned. I would like to note that VA's technology assessment program stated that such practices have ethical implications, and I believe that such system-wide clinical decisionmaking is both difficult and dangerous, particularly when the system, such as the VA, is structurally encumbered from responding rapidly to changing health care practices and needs. I believe this, in part, because of the FDA's specific efforts to identify adverse drug events from therapeutic interchanges for patients in private managed care plans.

Further, while acknowledging that veterans are more ill than average and have some special health needs, the VA's dictum against newly approved medicines ignores the clinical value of new, innovative medicines. This VA practice again highlights my concern about making system-wide clinical policies and decisions without the treating physician truly being able to individualize care for a particular patient.

Incentives for a VA physician to comply with the VA's formulary policies is another factor which may be affecting the quality of care for veterans. Although there appears to be very little analysis in this area and little data, because of the centralized nature of the VA's management and the fact that VA managers are attempting to monitor formulary compliance, as I believe the GAO commented upon in their study, there should be concerns about what incentives and disincentives VA physicians are facing in providing pharmaceutical care to veterans.

Several surveys have also been conducted to assess the quality of the VA's pharmaceutical management systems. One study done by Yankelovich captured somewhat, the GAO, I think, used the term "experiential data" on patient outcomes, and they found that 23 percent of 418 VA physicians surveyed personally had had a patient that had experienced a negative outcome because of problems accessing medicines within the VA system. I find this to be of concern, particularly when it's combined with the IOM's finding that the VA patient safety event registry did "not appear to be a reliable source for identifying adverse drug events."

Another worrisome finding is the VA's collection and analysis of data, as was discussed earlier, to assess outcomes concerning its national formulary system have been insufficient and their oversight in the area has not been comprehensive, nor integrated with other aspects of quality monitoring improvement. This contrasts with the VA's data showing utilization changes and cost savings. It is my belief that this difference in data collection reflects prioritizations within the VA management. Overall, the VA's pharmaceutical management practices could be viewed as a large experiment where only a few of the possible effects were chosen for monitoring and analysis.

Because the VA is often compared to the private sector, it is important to appreciate differences between veterans obtaining care in VA facilities and patients in private health plans. Basically, this comes down to two areas. The veterans receiving care at the VA

are more ill than average, with greater needs for substance abuse and mental health treatments, and they need specialized services that the private health plans haven't generally developed in their systems.

And second, because many veterans lack financial means, they do not have the other choices of health care that private patients have. The competitive model of private health plans includes financial-based incentives to use certain types of care, and this is not applicable to the VA.

Just as the veteran patients are different than private sector patients, the veterans' health system operates very differently from private health plans. One striking example of these differences is the VA's ability to have pharmacists enforce therapeutic substitution policies and give veterans a medicine different from what their treating physician prescribed. Such practices, to the extent they are used to implement the VA's pharmaceutical policies, are very troubling. In fact, the VA-endorsed Principles of a Sound Drug Formulary System specifically states, "Therapeutic substitution, the dispensing of therapeutic alternatives without the prescriber's approval, is illegal and should not be allowed."

In conclusion, the veterans' health system is different from other private health systems in its financing and structure and it is important——

Chairman ROCKEFELLER. Could you go over that last statement just again? I am just grateful there is not a stenographer handling your testimony, because you are moving quite quickly——

Dr. MILLER. I am sorry.

Chairman ROCKEFELLER. It is fine. We can all understand it. But could you go over the last one again——

Dr. MILLER. About the VA pharmacists dispensing a different medicine?

Chairman ROCKEFELLER. Yes, that it should not be allowed, et cetera.

Dr. MILLER. Basically, this relates to State practice of pharmacy laws, and the VA as a Federal program is not subject to those State laws. That is my understanding of the operation of the system. There has been some documentation at local VA facilities where the directors have been——

Chairman ROCKEFELLER. But I thought you were saying something to the effect that—I had the feeling it was getting into patent extension or something of that sort, that you should not be able to do substitutes——

Dr. MILLER. The quote from "The Principles of a Sound Drug Formulary System," which is a document endorsed by the VA as well as several other national organizations, like the AMA, Association of Health System Pharmacists, and I can read the quote again. It says, "Therapeutic substitution, the dispensior of therapeutic alternatives without the prescriber's approval, is illegal and should not be allowed," and that illegality refers to private sector pharmacies. The VA is not subject to those State laws because it is a Federal system.

Chairman ROCKEFELLER. That is interesting. I will get some comments on that afterwards. Excuse me. Go ahead.

Dr. MILLER. In conclusion, the VA is different than a private health system. It is an important component of the U.S. health system, filling a unique role in providing health care service to American veterans and training American physicians to practice medicine in a manner which many may carry outside of the VA system. Over 3 million veterans receive care from the VA, but these veterans are often more vulnerable, both clinically and economically than patients in private health plans who are protected by their ability to choose other health providers or treatments not preferred or offered by their health plans.

To truly evaluate the effectiveness of a health system, and any proposed changes, clinical outcomes need to be the gold standard that are looked at. In evaluating health systems, it is important to look at four key areas: one, how access is provided for the health care services and the effects access limitations have on outcomes; two, how innovations are adopted by the system to improve outcomes; three, how many proposed changes fit into the vision of that system for the future; and four, what is the plan for getting from where the system is today to that envisioned in the future?

Recognizing the unique characteristics and limitations of the veterans' health system, all these principles can be applied to it and its management of pharmaceutical access and delivery.

I thank the chair and welcome any comments. I apologize for going over.

Chairman ROCKEFELLER. No, it is OK. Thank you, Dr. Miller.

[The prepared statement of Dr. Miller follows:]

PREPARED STATEMENT OF MICHAEL D. MILLER, M.D., CONSULTANT TO THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATION (PhRMA)

Mr. Chairman, Members of the Committee. I am honored and pleased to be here today to share some of my thoughts on the Veterans Health Administration's (VHA) management of pharmaceuticals and on the findings of the Institute of Medicines'[1] and the General Accounting Office's[2] studies of this issue. For the last year and a half I have been a health policy and communications Analyst, Consultant and Educator focusing on issues and projects related to the quality of healthcare and the development and use of new medical treatments. In this capacity I have given talks and participated in over 40 meetings across the country discussing these topics. I am currently a Consultant to the Pharmaceutical Research and Manufactures of America, the Association representing America's Research-based Pharmaceutical companies, but I want to make clear that the views I am expressing are my own.

INTRODUCTION

It is important to remember that the current focus on the VA's National Formulary is due to the clinical and economic value of modern pharmaceuticals. Over the past 10–20 years pharmaceuticals have become a more important part of healthcare, and patients and providers are increasingly looking to pharmaceuticals as their preferred treatment option. Due to their clinical importance and value, providers and consumers of healthcare are also seeing a growing percentage of their healthcare spending going to pharmaceuticals. In sum, the pharmaceutical industry has succeeded in bringing many better treatment options to the bedside and the pharmacy shelf, but with this success has come increased scrutiny from those paying for healthcare services. The VHA is no exception, and as it has been reorganizing the Veterans Healthcare System, it has had to confront pharmaceutical management issues. Although much of the reorganization has been positive, such as expanding outpatient clinics, I believe that some of the clinical aspects of their man-

[1] "Description and Analysis of the VA National Formulary," IOM 2000

[2] "VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs," GAO–01–183

agement of pharmaceutical care have been problematic for veterans and the quality of their healthcare.[3]

There are three key points I would like to make: First, the quality of care received by America's veterans should be the focus for assessing the VHA's pharmacy programs. Second, veterans receiving care from the Veterans Healthcare System have significant differences from patients receiving care through private managed care plans or state Medicaid programs. Third, although the VHA's formulary and pharmacy practices are often compared to those employed by private managed care plans and state Medicaid agencies, the VHA, as a government program must operate differently, and it is limited in some of the ways it can deliver and manage the healthcare it delivers to veterans. I will expand upon each of these areas, and conclude with some thoughts about future directions.

QUALITY OF HEALTHCARE FOR VETERANS

Quality in healthcare is often defined by different individuals and experts in a variety of ways. For example, the IOM asserted that healthcare quality "can be assessed by examining the structure, process, and outcomes of delivery of care." Another frequently used measure of quality is patients' satisfaction, which is often measured as waiting times for both an appointment and within the healthcare system.[4]

The definitions I prefer, focus on the individual patient. One such definition is, "The right treatment for the right patient at the right time." Assessing quality at the individual patient level is encompassed through outcome measurements. As the VA's Primer on Outcomes states, "Outcomes measurements help bring the focus of the entire health care delivery system back to the patient. Rigorous and continuous evaluation of the processes of care through outcomes measurement and analysis will ultimately improve the quality of care."[5] The "Principles of a Sound Drug Formulary System," which was endorsed by the VA, "recognizes that patient care may be compromised if its formulary system is not optimally developed, organized and administered.[6]

As quality can be defined in many different ways, can it can also be analyzed in many different ways. The IOM and the GAO have each reviewed and analyzed the VHA's pharmacy system, and I would like to highlight some of their findings and comment upon some of the limitations of their studies. I will make these comments about the studies' findings and limitations not to criticize in any way the good work of the IOM or the GAO, but rather as a starting point to suggest approaches and promote thinking about future analyses of the Veterans Health System and VHA management because I strongly believe it is important to understand what we know—and what we don't know—in order to plan for future improvements.

One of the worrisome findings in both the IOM and GAO studies is that the VA's activities in collecting and analyzing data to assess outcomes concerning its National Formulary system have been insufficient or lacking, and thus overall VHA's oversight in this area has not been comprehensive nor integrated with other aspects of quality monitoring and improvement. This contrasts both with the VA's Outcomes Primer statement that, "Reliable data collection is necessary to develop strong evidence for health care decision making," and the VA's data showing utilization changes and cost savings. Although the IOM did try and assess the effects of these utilization changes on veterans' healthcare, they were restricted in their ability to do so by the VA's data limitations and because they were conducting a retrospective analysis rather than being able to evaluate the effects prospectively during implementation of the formulary policies.

The IOM did find that hospitalizations for certain heart and ulcer conditions did not change with the implementation of restrictions for medicines for these illnesses. Such a finding is in some ways reassuring that the outcomes for patients with these conditions did not change. However, this conclusion could be questioned because, in

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[3] Part of the challenge of modern healthcare is integrating the management of all components and options of the healthcare delivery system. It is easier to manage each component—and its budget—separately, but such an approach creates barriers for capitalizing on the benefits of new innovations, both in technology such as pharmaceuticals, and in processes for delivering care, such as disease management programs.

[4] In July 1999 Testimony, the GAO found that "Currently, the VA does not track information on primary and specialty clinic appointment waiting times." GAO/T-HEHS-99-158

[5] "Using Outcomes to Improve Health Care Decision Making," Zimmerman, Daley, Kizer and Feussner, VA and AHSR, 1997

[6] October 2000, "Principles of a Sound Drug Formulary System," was endorsed by the VA's PBM, the AMA, the Academy of Managed Care Pharmacy, the Alliance of Community Health Plans, the American Society of Health-System Pharmacists, the National Business Coalition on Health, and the U.S. Pharmacopeia.

part, it assumes that the percentage of veterans using the Veterans Healthcare System who have outside insurance coverage, such has Medicare, has not changed and similarly that veterans use of non-VA facilities has not changed. These assumptions, and hence the IOM's conclusion may be questioned in light of the GAO's 1999 finding that "several [VISN] directors commented that they are experiencing increased demand by veterans whose primary care is provided elsewhere but who obtain from the VA specialty care and services not covered by private insurance or Medicare."[7][8]

In addition, measuring inpatient admissions as a surrogate for outcomes would also miss adverse events treated in VA outpatient clinics, as well as in private outpatient settings. Given that the IOM also found that the VA's Patient Safety Event Registry "does not appear to be a reliable source for identifying ADEs (Adverse Drug Events)," this could be another factor complicating the evaluation of the effects of the VA's National Formulary and pharmacy policies on the quality of healthcare for veterans.[9]

Therefore, without measuring the utilization of healthcare services for individual patients both within and outside of the Veterans Healthcare System, it is uncertain how total utilization and outcomes have been affected by the VA's formulary policies.

The IOM also found some problems with the VA's non-formulary exceptions process and therapeutic interchange practices. Both of these policies affect the individualized nature of clinical medicine. Although we would all like to believe that the practice of medicine is much more a science than an art, individual patient variation still plays a significant part in clinical care, and as the VA's Technical Advisory Panel concluded, population-based approaches to healthcare decision making and delivery, such as practiced by managed care plans and being adopted by the VA, have ethical implications.[10] The changing nature of medicine—with new knowledge replacing old dictums—also makes such system-wide clinical decision-making both difficult and dangerous, particularly when the system is structurally encumbered from changing rapidly.

Another challenge the VHA faces in making decisions about therapeutic interchange is the limitations of the data available to them about individual patient variability between medicines. The FDA only achieves such conclusion about the interchangeability of medicines for generic versions of already approved medicines based upon bioequivalency data—not for different chemical compounds. In fact, the FDA was so concerned about adverse drug events (ADEs) from therapeutic interchange in private health systems, that it specifically launched an effort looking for such ADEs through its MedWatch program.[11]

Several other factors complicate the reliability of conclusions made when analyzing data about any group of medicines in a class. These include:

- The different natures of the populations used in the individual studies;
- The reporting of group averages can often be misleading when trying to make efficacy comparisons; [12] and

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[7] GAO/T–HEHS–99–109

[8] It could be argued that if VA patients' use of private sector health facilities has not changed then the conclusion would be valid. However, the availability of emergency care differs between the VA and private health facilities, and thus if there were an increase in outside insurance coverage and acute adverse events, then the utilization of these non-VA health services might be expected to increase disproportionately.

[9] The VA endorsed, "Principles of a Sound Drug Formulary System," calls for a formulary system that "Provides for the monitoring, reporting, and analysis of adverse results of drug therapy (e.g., adverse drug reactions, medication errors) to continuously improve quality of care.

[10] The VA's Technology Assessment Program 1996 report on issues related to transferring managed care principles to the VA stated that the following managed care principles were used by private health plans that would be appropriate "models to the VA:

- care should be integrated throughout disease processes;
- resource use should be managed through the management of quality, i.e., by the management of variation;
- incentives should be aligned to the well-being of the enrolled population, not to the punishment of physicians for individual clinical decisions;
- the ethical impact of a population-based approach to health care decision making and delivery should be addressed through technology assessment."

[11] System-wide therapeutic interchange policies are an example of a population-based approach to healthcare decision-making and delivery.

[12] For example, if two medicines have both been shown to be effective in treating a disease in 70% of patients in clinical trials, this may—or may not—mean they are comparable because each medicine may have a 70% likelihood of being effective in any given individual, but it's success or failure in an individual may not predict likelihood of the success of failure of the other medicine in the same patient. This is the situation for the SSRI class of medicines used to treat depression.

• If the study populations are less ill than the population which the conclusions are going to be applied to, then because of the greater disease burden in the real-life population, such as that seen at VA health centers, there is a greater possibility of adverse events due to the higher rates of concurrent diseases and medicines used.

These factors all contribute to the different results produced in a clinical trial, where conditions and patients are closely monitored, versus what happens in real world clinical practice.[13] The VA uses this argument, along with the veterans being more ill than average patients, for not making medicines readily available once they are approved by the FDA. Thus, the VA argues that the data on newly approved drugs is not sufficient to safely provide them to veterans, but it uses similar data to decide which medicines are therapeutically interchangeable. Further, acknowledging that veterans are more ill than average, and some have specialized health needs, the VA's dictum against newly approved medicines ignores the clinical value of innovative medicines. This knotted logic illustrates my concern about making system-wide clinical policies and decisions without the treating physician being able to truly individualize care for a particular patient.[14] The incentives for VHA physicians to comply with the VHA's formulary policies and directives are another factor concerning the effects the VHA's formulary system has on the quality of care for veterans. Although there appears to be little analysis in this area, the centralized nature of the VHA's management, and because VHA local and regional managers are attempting to monitor formulary compliance, raises questions about what incentives and disincentives VHA physicians are facing in providing care to veterans.

How concerned should we be about these pharmaceutical limitations and practices for the individual veteran receiving healthcare from the VHA? The GAO found that 10 percent of prescriptions were for drugs in the VA's closed classes.[15] [16] How, many veterans this affects are unknown. The best way to determine this would be through a comprehensive, patient-based analysis of the utilization of the restricted drugs and classes in the VA's National Formulary.

Several surveys have also been conducted to assess the quality of the VHA's pharmaceutical management systems. Each of these surveys has its methodological problems and limitations. The IOM identified some of these in its review of both VHA's written survey and the telephone survey conducted by Yankelovich Partners. The GAO also conducted a mail survey for their January 2001 Report.[17] The Yankelovich survey captured some "experiential data"—to borrow a term from the GAO's lexicon—on actual patient outcomes: Their survey found that 23% of the 418 VA physicians surveyed had personally had a patient experience a negative outcome because of problems accessing medicines within the VA's National Formulary system. I find this to be of concern, particularly when it is combined with the IOM's finding that as of the time of their survey, the VA's Patient Safety Event Registry did "not appear to be a reliable source for identifying ADEs."

These conclusions are consistent with the GAO's and the IOM's findings that the VA's National Formulary system has been implemented without sufficient data collection and quality focused oversight tools in place. While the GAO in part focused on the problems the VA has in ensuring compliance with the National Formulary policies and "standardizations," I am much more concerned about the lack of data and oversight related to quality of care and outcomes measurements. The VA's National Formulary could be viewed as a large experiment where only a few of the possible effects were chosen for monitoring and analysis. Specifically, the VA has closely monitored and reported effects on utilization and costs, but the effects on quality of patient care—albeit much more difficult parameters to measure—have not received the nearly the same attention by the VA. (These same data inadequacies may also exist within many private health plans, and in the following sections I will

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[13] The VA's Outcomes Primer (1997) states, "clinical epidemiologists have sought to establish "real world" effectiveness of diagnostic tests and treatments. These researchers have been concerned not only with the "intervening" variables that characterize disease status, but with the "patient outcome" variables that characterize patients' health status."

[14] The VA asserts that individual physicians can obtain off-formulary medicines for their patients when need, but the GAO in their January 2001 study found that 60% of the providers they surveyed said the average waiting time for non-formulary approvals was 9 days. GAO/HEHS–00–34

[15] GAO December 1999 Study, "VA Health Care: VA's Management of Drugs on Its National Formulary."

[16] A 1998 analysis comparing IMS data and the medicines excluded from the VA's closed classes found that the VA's National Formulary excluded 12 of the 100 medicines most frequently prescribed in the private market. Since the list of 100 medicines included generic medicines, the percentage of excluded innovative medicines was greater than 12%, i.e. closer to 25%.

[17] Of concern in the GAO survey was that they received responses from "many prescribers" who wrote only a few prescriptions, and thus the average findings may not reflect the experience of active clinicians.

discuss the implications of the differences between the VHA and other health systems.)

The bottom line is that unless outcomes and adverse events are examined, changes can't be made to improve outcomes and avoid adverse events, and the effects on quality brought about by changes to the systems and processes will not be known until secondary and more significant adverse events become apparent. This is analogous to shaving your face in a fogged-up mirror. You may know that the blade needs to changed because you face feels rough or you find blood on your fingers, but wiping off the mirror and looking at what you are doing is certainly a both a quicker and cheaper solution in the long run because preventing adverse outcomes is better than treating them.

DIFFERENCES BETWEEN VA PATIENTS AND PATIENTS IN PRIVATE HEALTH PLAN OR MEDICAID

Although private health plans are often criticized for having the same lack of data collection priorities as described above, it is important to appreciate the differences between veterans obtaining care at VHA facilities and patients obtaining care at private health plans, and the implications this can have for the quality of healthcare veterans receive.

Not only is the VA caring "for a population that is disproportionately elderly and ill,"[18][19][20] but many also lack the economic resources to choose another option for their healthcare, i.e. they can't vote with their feet to see another doctor, and they can't afford to pay out-of-pocket for a medicine the VA won't provide for them. These differences between the Veterans Healthcare System's patient population and the population cared for through private health plans have significant implications for comparing their management practices.[21]

Of course, an exception to statement that the veterans using the Veterans Healthcare System lack economic resources would be those veterans who are also Medicare beneficiaries, and are accessing the VA for benefits Medicare does not currently provide, i.e. pharmaceuticals. Within this group of patients, there are certainly individuals who can afford to purchase medicines not provided by the VA. This leads to a troubling practice that I call "healthcare disintegration." By that I mean, the patient's team of healthcare providers is divided so not only may the patient be receiving prescriptions from more than one physician, but they are almost certainly having prescriptions filled by more than one pharmacist—who may not know what other medicines the other patient is taking.[22]

The significance of these clinical and economic factors is that systems for delivering healthcare, and of financial incentives for patients and providers, cannot always be readily transferred from the one system to another. In the clinical arena, delivery systems developed for private sector health systems may not fit the needs of patient populations with greater needs for mental health and substance abuse treatments. In the economic area, private health plans use financial incentives for patients and providers to use certain medicines, and the structure of these incentives have been evolving very rapidly over the last decade, from closed formularies to three tiered, to now four or even five tiered formularies. One interesting private sector health plan utilizes a program called 10–50–1000 to create financial incentives for patients and their physicians: A $10 co-payment for preferred brand medicines, a 50% co-payment for a non-preferred brand medicine, and an annual $1000 out-of-pocket cap. Another interesting facet of some private health plan formularies involves allowing a patient to pay a lower tier's co-payment amount if for medical reasons they cannot take the preferred medicine in that therapeutic class. The decision about this lower co-payment is made within the health plans local administration. Innovations like this are not possible within the Veterans Healthcare System

[18] IOM Study—characterization in Committee Chair's Preface.

[19] -9 million Veterans are Medicare beneficiaries.

[20] Estimates of Hepatitis C prevalence among veterans were put at 8–10 percent in 1999, (GAO/T–HEHS–99–158), and over 670,000 Veterans treated by the VA have mental illnesses, and 366,000 have a substance abuse diagnosis. (VA Testimony, 6/20/2001)

[21] Similarly, VA patients are very different from those covered by Medicaid. Simply put, the Medicaid patients are younger women and children, or elderly in long-term care settings, whereas the VA patients are predominantly male and elderly.

[22] I recently encountered this situation with a family friend with diabetes and cardiovascular conditions. The VA provides him with some of his medicines, and he obtains those the VA will not provide from the local pharmacy. Neither pharmacist knows or has records about all the medicines he is taking. This not only complicates his healthcare, potentially putting him at increased risk for drug-drug interactions, but it also undermines any analysis based solely upon VA data. This type of "disintegration" of the patient's healthcare team is also one of the hidden hazards of purchasing medicine via the Internet or from foreign sources.

because of its centralized decision-making structure and standardization, and the economic limitations of many VA patients.

LIMITATIONS OF THE VA HEALTH SYSTEM AS A GOVERNMENT PROGRAM

Although significant restructuring of the VA's Health System has occurred in the past several years, it still differs from private health systems in many ways, including:

- Limited flexibility in managing its annual budget because such a great percentage of it is committed to relatively fixed cost areas such as personnel and facilities;[23]
- Limited flexibility in hiring or firing of personnel, and buying or selling buildings or land;
- Access to government monsopony benefits such as the Federal Supply Schedule prices for pharmaceuticals which already provides the VHA with procurement prices lower than those available in the private market;
- Regulatory procedures must frequently be followed to change policies and practices; and
- Limited ability to change the structure of benefits.

In constant, private sector health plans are constrained by the terms of the contracts they have with patients, employers, and providers, as well as by some state and Federal laws. Specifically, as a Federal program, state laws do not bind the VA and thus it can bestow privileges on health care providers beyond what state laws would allow. For example, the VA is able to allow VA pharmacists to enforce therapeutic substitution policies, and give the veteran a medicine different from what their treating physician prescribed without a new prescription order from a physician. The VA endorsed "Principles of a Sound Drug Formulary System" specifically states that "Therapeutic substitution, the dispending of therapeutic alternatives without the prescriber's approval, is illegal and should not be allowed."

Overall, private health plans have much greater flexibility than the VA, and each faces different directives and forces when working to respond to the challenges of a changing healthcare environment and evolutions in biomedical science. For example, because so much of the VA's budget it consumed by relatively fixed cost areas, in times of financial constraints, savings programs must be directed towards budget items that are not fixed, e.g. pharmaceuticals.[24]

These budgetary constraints drive the VA's decision making into silo or sector thinking and management. Private health plans, because of their greater structural and financial flexibility, can more easily integrate the management of all components of their health delivery system, and thus explicitly attempt to initiate practices which will produce cost savings in one area while knowingly increase costs in another area. For example, a large health plan instituted a disease management program for patients with congestive heart failure. After one year's experience with over 1,900 patients, they found they for these patients, hospitalization costs had decreased 78%, outpatient pharmaceutical spending had increased 60% ($243,000), with the net savings in caring for these patients totaling $9.3 million.[25] In addition, this intervention produced better clinical outcomes, with the patients better able to perform activities of daily living, and their mortality rate was only 10 percent compared to an expected 25 percent. This type of integrated management is difficult for the VA because of it's data limitations, and so much of its spending is for fixed cost items and thus it cannot realize savings from such utilization substitutions.[26]

Private health plans also have much greater flexibility in their arrangements with providers and with their patients. For example, health plans can relatively quickly, reorganize contracts with providers, reprioritize co-payments and deductibles payments due from patients, sell off assets and even change premium structures. Thus, they have much greater flexibility in managing financial constraints, and responding to the changing nature of clinical medicine by changing benefit designs and their structure for delivering healthcare.

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[23] "VA's massive, aged infrastructure could be the biggest obstacle confronting VA's ongoing transformation efforts." GAO/T–HEHS–99–109

[24] Pharmaceuticals represent the single largest component of these "unfixed" expenditures—even though within the VHA's overall spending, pharmaceuticals are very small compared to facilities and personnel costs. An analysis I conducted several years ago showed that ~65% of the VA's health budget was spent on inflexible expenditures such as personnel and facilities, while about 9% was spent on pharmaceuticals.

[25] 1996 Year-Long Study of 1,915 Humana Members reported in "Managed Care Pharmacy," April 1998, pp 42–44

[26] In 1999, the GAO stated "VA's data systems do not fully track treatment specific costs, making it difficult for VA to determine the exact cost savings it could realize by discontinuing care to some veterans or reducing benefits." GAO/T–HEHS–99–158

CONCLUSIONS

The Veterans Healthcare System is a unique component of the US healthcare system, serving an important role in providing healthcare services to America's veterans. Because of it's unique character, comparing the Veterans Healthcare System to other health systems must include a recognition of the differences between the VA and non-governmental providers and financers of health care—both here in the US and in other countries.

While the VHA provides healthcare to over 3 million US veterans each year, these individuals are not a representative sample of Americans, but rather they are predominantly male, older, have more healthcare problems and needs than average, and have lower financial resources. These last two points, while well known to VA observers, are important because together they mean that many of these patients are more vulnerable both clinically and economically than patients in private health plans who are protected by their ability to choose other health plans, or treatments not preferred nor offered by their health plans.

To truly evaluate the effectiveness of a health system, and any changes being made to "improve" it, clinical outcomes are the gold standard. Recognizing the difficulty in measuring and analyzing data for clinical outcomes does not change their importance. Rather, it highlights the importance of examining whatever analyses are available, and asking what are the limitations of these analyses and what insight can they provide into the effects changes to any component of the health system may be having for actual clinical outcomes.

Overall, because outcomes are the key goal, in evaluating any health system it is important to look at four key areas of structure and planning: 1. How access is provided to health care services and the effect access limits and practices have on clinical outcomes; 2. How innovations are adopted by the system to improve outcomes; 3. In planning for future improvements to a health system, what should this future looks like, i.e., what is the vision; and 4. What is the plan for getting to that envisioned future from where the system exists today. Recognizing its unique characteristics and limitations, all these principles can be applied to the Veterans Healthcare System, and its management of pharmaceutical access and delivery.

Chairman ROCKEFELLER. Is Dr. Garthwaite still here?

Mr. OGDEN. No, Dr. Garthwaite left, but I am here.

Chairman ROCKEFELLER. You are here, that is right. John, you are here. The reason I wanted to know is because I think you used the percentage 23 percent——

Dr. MILLER. That was in the Yankelovich survey.

Chairman ROCKEFELLER. Yes, and that there was a bad result or a bad outcome or a less than desirable outcome. I have heard this used so much over the last number of years, and yet I have actually never heard it defined very well. Dr. Herdman, I might call on you and you can give us that, and you, John Ogden, if you care to.

How does that break down? What is the meaning of either an overlapping or conflicting prescription, as opposed to simply taking the wrong ones, as opposed to computer mistakes, as opposed to the confusion at whatever magnitude? Let us take the 23 percent for the moment, regardless of whether it is 13 or 23, and let us take it and break it down as much as you can, as you understand the problem of misuse of prescriptions or overuse of prescriptions or conflicting use of prescriptions, or whatever. I do not ask for absolute accuracy. I ask for a sense, because I have heard this used so often and I have never heard it broken down properly.

Dr. MILLER. Mr. Chairman, would you like me to respond and explain the——

Chairman ROCKEFELLER. That would be fine, too.

Dr. MILLER. The number came out of a Yankelovich phone survey of VA physicians and reflected those physicians feeling that their patient had a negative outcome because of some limitation in——

Chairman ROCKEFELLER. No, I understand what was positive. What I am trying to get is underneath that, what the explanation might be.

Dr. MILLER. What those adverse events were?

Chairman ROCKEFELLER. What is it they observe? Where do they think these mistakes are made, et cetera?

Dr. HERDMAN. The Yankelovich survey, if I could, Senator, is a survey basically of physicians' attitudes about a national formulary and what they are saying is they don't like it or they have trouble getting medications they need or their patients are suffering bad outcomes because the formulary——

Chairman ROCKEFELLER. All of which I understand, Dr. Herdman. I am just trying to get a sense of how, in a rough way, does that break down episodically? What are the causes of that?

Dr. HERDMAN. I don't think that the survey helps you find that. If you are thinking——

Chairman ROCKEFELLER. I know that. I understand that. I am trying to just——

Dr. HERDMAN. I am not sure what the percent in various categories is—maybe John Ogden can help us with this—is of the various problems that you have in the pharmacy benefit or prescribing, whether the adverse events are allergies or the patient took the wrong dose or the physician prescribed the wrong dose or the pharmacist dispensed the wrong dose or there was an interaction between the drug that the patient was already on and the new drug that was prescribed. Those are an array of problems which can occur in a drug treatment situation. There are reports in literature about how those things, the numbers of those and the percents in the various categories, if that is what you are looking for.

Dr. MILLER. I think the VA has done a good job in reporting about their use of bar code and other things to prevent dispensing of the wrong medicine to the patient, which is one area where you can have a medical error resulting in an adverse outcome.

The other kinds of things that can happen, as Dr. Herdman said, you can get drug-drug interactions, and that brings up one concern that I have and it relates to Medicare, is some veterans may be getting some of their medicines from the VA and some of their medicines outside of the VA.

Chairman ROCKEFELLER. That is what I am trying to get at. John, do you have some——

Mr. OGDEN. I don't have any numbers on that, but I would say that is an accurate statement.

Chairman ROCKEFELLER. Do you have anything more you could add, into a microphone?

Mr. OGDEN. On that issue, or on the whole issue——

Chairman ROCKEFELLER. On that issue.

Mr. OGDEN. I would say that you probably have veterans who have those eligibilities, those dual or triple eligibilities, that do go to the different systems, and because the informatics capability external to VA, feeding into VA or interacting with VA, doesn't exist, that there is a possibility of drug-drug interactions in that situation.

Chairman ROCKEFELLER. And would that be because they would fear that they would run out, let us say, of a prescription and they wanted to make sure that they had enough for several months? Would that be——

Mr. OGDEN. I don't believe that——

Chairman ROCKEFELLER. Why would they——

Mr. OGDEN. Why they would shop, if you will?

Chairman ROCKEFELLER. Yes.

Mr. OGDEN. It could be convenience. It could be access, you know, where they happen to be at a point in time geographically in the country.

Chairman ROCKEFELLER. What percentage of bad outcomes can result in very serious health damage?

Mr. OGDEN. Well, I am not a physician——

Chairman ROCKEFELLER. In general terms. In general terms.

Mr. OGDEN. I don't think I am the person to answer that question, but drugs, in this country, drugs approved by the Food and Drug Administration are generally safe when taken as directed.

Chairman ROCKEFELLER. As prescribed.

Mr. OGDEN. How many adverse events occur because patients take drugs that——

Chairman ROCKEFELLER. Or take them on their own. I mean, there is the classic situation, and whenever I think about this, I think of retired coal miners, who average 78 to 80 years old. You open up the medicine cabinet in their bathrooms and there may be 12 to 15 bottles of pills and they may take as many as 12 different kinds of pills a day. So inherent in that—and it is not a far reach from there to a veteran—is a tremendous capacity for confusion, the drug already having been dispensed, the little paper that comes in the bag that says what you can't mix it with, et cetera, already having been long since deposited in the trash can, you know, where these confusions come from.

Mr. OGDEN. Well, you absolutely make an excellent point. When you think about the VA, and Dr. Miller described the VA as being different, if, in our case, the veteran accesses the VA health care system for most of their medical care needs, which subsequently would include pharmaceuticals, those pharmaceuticals are in the VA automated medical records, so that screening is taking place.

Chairman ROCKEFELLER. Automatically?

Mr. OGDEN. Automatically. In the private sector, if you and I go down to the local drug store and present our prescription, they are screening your prescription, as well, but their screen only includes those prescriptions that you presented and subsequently received from that drug store. If a patient also utilizes another drug store 3 miles away or 5 miles away, that screening doesn't take place.

So it does lend some credence to interconnectivity, and I appreciate the issue of patient confidentiality, but from a patient safety and quality of care perspective, there is an absolute need for patients, for people like you and I and our families, to choose a system, choose a pharmacy and stick with that pharmacy, because you can be reasonably assured, then, that those cross-checks are taking place, whether it is Giant, whether it is CVS, whether it is XYZ pharmacy.

Dr. HERDMAN. There are, Senator, an enormous number of adverse drug events in this country every year for all the various reasons we have been talking about. It seems to me, that there is information to get at the numbers and reasons for those, the errors—I think there is a section in the IOM report, "To Err is Human," a medical errors report. I am not sure staff has seen that. I would be happy to send you a copy, which describes some of this and ways in which people can avoid those drug errors.

Ms. BASCETTA. Mr. Chairman, I would——

Chairman ROCKEFELLER. You see, that is precisely the point. It is a syndrome we get into here in Washington, it seems to me, that we discuss things as we think they should be, and, indeed, as they often should be. But our discussing of it, even passing rules, regulations, or laws about it, doesn't necessarily project it any further than Bethesda, MD. I mean, it is of enormous concern to me.

The point that you made—and I recognize this is off-point in some respects, but it is on-point as far as I am concerned—that if you decide to go to a certain pharmacy, and I will just use my own example. I had three root canals taken on the same tooth. I was not particularly grateful for that experience, but I had to deal with it, and each time, I had to go get penicillin in case there was inflammation. In one case, I was going off to Japan, that kind of thing.

And so I was, in effect—I have no particular allegiance to a pharmacy, and so it was almost a question of where I chose to stop. And in each case, where I chose to stop, I had to wait an hour because they tended to be large pharmacies with lots of people waiting, or in some cases large pharmacies with nobody waiting, in which case the 1-hour totally perplexed me——

[Laughter.]

Chairman ROCKEFELLER [continuing]. But the point was, I waited an hour, which I really don't have, although I am not important in that respect, but I did it. Well, that could have driven me to another pharmacy, couldn't it, where they would not have had any record of these previous root canals, whatever, and it is a very important point, and it is all assuming consumer sophistication. I think that my understanding of those things might be a little bit better, let us say, than some other people, so this is a huge problem.

As I said, the suggestions that you have are exactly right. There is a wonderful article in today's Post by Dean Ornish, whom I happen to admire very much, about pace of life and what you eat and all the rest of it, and I am going to read it when I get home tonight. I do not know how many other people are going to read it. So what is written doesn't necessarily mean what people do. That is my point.

Dr. MILLER. Can I make one further comment, Senator?

Chairman ROCKEFELLER. Yes.

Dr. MILLER. The problem is only going to get worse as we develop more treatments to treat chronic diseases as our population ages, because the more medicines somebody takes, the more concomitant illnesses they have, the potential for drug-drug interactions or just an adverse event from a single drug because of other illnesses increases.

So, as Dr. Herdman said, to err is human. I think we need to take the perspective that health care is, by nature, a little bit messy. It is still as much art as it is science, which adds the complexity of trying to figure out what is the best thing to do for individual patients. However, part of the problem I have, and I understand the GAO's perspective, and the work it does, but standardization and uniformity are not always the best thing for quality of care. They may have value in a bureaucracy, in administration of things, but health care is a little different than just producing something where everything is the same, whether it is cars or pens or water glasses.

Ms. BASCETTA. Mr. Chairman?

Chairman ROCKEFELLER. You have your chance. Yes?

Ms. BASCETTA. As long as standardization is clinically driven, and I think John Ogden would agree that that is, in fact, the essential underpinnings of the VA's decisions, then it is appropriate. Of course, the other piece of that is you have to balance local needs and individual needs. That is why getting better oversight and control of the non-formulary process is so important to us.

I would like to comment about the IOM study. I think that Mr. Herdman is exactly correct that there is data in there, although I think it is more heavily looking at inpatient problems with medication errors and adverse events. It won't help us today, but for the future, VA has a patient safety initiative that is quite extensive, and I know that what they are doing is they are collecting data on actual harm that has been done as a result of an error, or potential harm. Of course, there is much more in the potential harm area, fortunately, than in the actual harm area.

They are finding that so many reports are coming in on medication errors that, in fact, rather than doing an analysis of each of those incidents, they are aggregating them and they are going to be looking at what the causes of those errors are. So I would hope that when they have had more experience with that data base and with that initiative, we will learn something that will be useful.

Chairman ROCKEFELLER. OK. I want to get back to basics for a moment again with you, Ms. Bascetta, and that is that you have looked at a lot of projects in the VA health care system. Again, I go to this cost shifting matter that I discussed with the earlier panel. If the price of pharmaceuticals continues to rise, as I think we all understand it will, what do you think will be the effect on the VA as a health care system in its efficacy for veterans?

Ms. BASCETTA. As the effect would similarly be on the entire health care system, what happens is that if you are going to have a fixed amount of resources to spend on health care, if one component, in this case, drugs, rises disproportionately, you are going to crowd out other services. You have a couple—that is the simple answer. I mean, you have a couple of options. You can offer a less generous benefit package to a larger number of people or you can cut back on the number of people that you can serve or you can look for more money.

Chairman ROCKEFELLER. You see, that point has to be made very clearly, doesn't it——

Ms. BASCETTA. Yes, it does.

Chairman ROCKEFELLER [continuing]. Because this is a budgeted annual event, the VA health care system——

Ms. BASCETTA. That is correct.

Chairman ROCKEFELLER [continuing]. And if one thing goes up, something else has to come down.

Ms. BASCETTA. I think we have to be careful about oversimplifying, though, in the sense that there are lots of complicated analyses we could do to shed light on the problem. For example, we know that the priority seven veterans are coming in at a much higher rate than they were before eligibility reform. We credit the IG with coming up with the first quantitative information that supports the conventional wisdom that, in fact, they are coming for gap coverage.

As Dr. Garthwaite said, I don't know if we can extrapolate from VISN 8, but VA could take its PBM data base and match it against its enrollment data base to see, in fact, what the costs are, what the utilization costs are for pharmaceuticals for the sevens, and they can also do it by age, to see what the Medicare-eligible proportion of the population is that is using those services. They might have to go into the medical records to check if that was the sole utilization of those beneficiaries. I am not sure.

But it would be important to get a handle on that, and part of the reason that would be important is if sevens are, in fact, driving up disproportionately or in an absolute sense that proportion of the budget, then you might want to tailor a solution to that part of the population. You might want to see if you can raise copays there more if, in fact, the sevens have resources. There are other options that might become more evident as you further analyze the problem.

Chairman ROCKEFELLER. Thank you.

Dr. Herdman, I want to ask you this. You mentioned in your testimony that the Medicaid formularies are more open, as you put it, than the VHA's formulary, because those formularies are required to offer all drugs on the FSS, the Federal Supply Schedule, that manufacturers list for rebates. Now, this strikes me as curious. The VA runs the formulary situation, but veterans don't have easy access to those drugs, while Medicaid beneficiaries do. So I am kind of curious, does this make sense? How does one analyze this?

Dr. HERDMAN. Well, it is true that Medicaid is required to cover all the drugs which manufacturers list for rebates on the Federal Supply Schedule, and that is a lot of drugs. It is also true that they can exclude some drugs, as I am sure you know, the OBRA drugs, which is about 12 categories of drugs, so that those drugs aren't available under any circumstances unless a State chooses not to take that exclusion, and it is also true that Medicaid can enforce prior authorization for drugs, which does restrict access to the drugs that they choose to list as drugs that need prior authorization.

And Medicaid programs also have a history, as I am sure you know, of other limits on drugs. For example, you can only have three prescriptions a month or three prescriptions over a certain time period, or a prescription can only have so many items in it or limits like that, which aren't based on medical necessity or any scientific or medical analysis of patient need or drug treatment

science, they are just arbitrary limits to save costs. And generally, I think, the IOM found that they were counterproductive.

So that describes the Medicaid program. The VA has, I think it is fair to say, a more restricted formulary in general because it lists overall, as you know, 1,200 items, but those items are not all drugs. Actually, more like 600 items, varying, depending on the VISN or facility, are probably actually separate individual pharmaceutical drug products. So it is more restrictive from that perspective.

But unless you are in a closed or preferred class, I think it is fair to say, there is reasonable access. I appreciate Ms. Bascetta's point. We certainly agree with that, that some of the facilities, they do not stock all the drugs. They may be on the formulary, but they are not stocked or the formulary may vary and the adherence isn't perfect.

But leaving that aside, unless you are in the closed or preferred classes, you have pretty good access to the drugs that are on the formulary and we thought, the IOM thought, that the formulary had a very reasonable array of drug products to cover the kinds of health conditions which veterans came in with. So that seemed fair enough.

It is true that there are problems with the closed classes. Insofar as if you don't do well on the drug that is in the class, you have an adverse reaction, or there isn't a therapeutic alternate in that class really for you, or for any of a bunch of reasons that the VA itself lists, that you might not want to have the drug which is listed in the closed class. If the drug in the closed class or the preferred class or the committed use contract or the blanket purchase agreement or whatever, the restriction, is not the drug that you need and you are going to do well on, then you may have a problem and that is a restriction which, I think, often in Medicaid, you would not run into.

So as the report said, at the end of the day, in some ways, the VA national formulary is more restrictive, and in some ways, it is less restrictive than comparison private sector or public sector formularies, and you have to take the individual——

Chairman ROCKEFELLER. I understand. I understand. I am going to ask three more questions, and I am not going to hold you beyond that. This is for you, Dr. Miller, and for you, Mr. Ogden, should you care to answer.

My question has to do with a recent example of problem issues with therapeutic interchange, and anybody else can comment. Obviously, I welcome that. Isn't there an issue right now, in fact, with automatic substitution of drugs to treat mental health patients? I am getting at the atypical antipsychotics matter.

Dr. MILLER. I have heard that there are some problems in this area, but I don't have any specific evidence to cite at this time. Although I am not intimately familiar with the VA's current policies in that area, the atypical antipsychotics, and treatment issues for mental illnesses, is a very interesting area because these people are very sick and oftentimes have multilayered issues, if you will, oftentimes with accessing health care. So if there is a problem with their treatment, it can lead to problems of trust of the provider and the health system. So making them jump through more hoops to

get what ultimately works for them could lead to problems for those patients.

Mr. OGDEN. I would care to comment if I could, please. There is no automatic substitution of the atypical antipsychotics in the VA health care system. The current VA National Formulary listing includes all of the atypical antipsychotics except for the brand new Pfizer product called Ziprasidone, which we are still developing. We have already developed the criteria for its use, but until more efficacy and safety data is available, we are not going to add it to the formulary right away.

What we are talking about in the case of the atypical antipsychotics is—not me or Dr. Garthwaite, but what mental health professionals are talking about in the field is you have a class of drugs, in this case, the newer atypical antipsychotics, the novel antipsychotics, in which there is no scientific evidence nor consensus at this point in time that drug A is better than drug B is better than drug C.

So what the field mental health professionals are contemplating and considering and, in fact, doing is in patients who have never been on an atypical antipsychotic or in patients who have had problems with the more traditional, the typical older antipsychotic drugs, what the mental health professionals are recommending is using an effective—or begin therapy with an effective, less expensive agent. That is what this is all about. It is not a fail-first policy. There is no fail-first policy. It is guidance that describes what I just explained to you.

And let me read from three documents that I have from three different health entities in this Nation concerning this matter. One of them is dated May 7, 1998.

> From a clinical standpoint, there are credible arguments for using each of these two medications, that is, Olanzapine and Risperidone, in various circumstances. However, the current price difference is extraordinary and it would be irresponsible to prescribe Olanzapine before prescribing Risperidone in clinical situations where either agent might readily be used.

That, in sum, is what we are talking about and what our mental health professionals are talking about in VA.

Here is another health plan from the Commonwealth of Massachusetts. Their Department of Corrections in their formulary dated October of 2000 said:

> Risperidone is the preferred atypical antipsychotic because it is felt that there is a similar therapeutic equivalency amongst the class of novel agents and the use of Risperidone is generally more cost effective than either Olanzapine or Quetiapine at comparative therapeutic doses. New patients being started on an atypical antipsychotic agent should begin with a treatment trial on Risperidone.

So that is the Commonwealth of Massachusetts, their Department of Corrections.

And the last system is the Henry Ford Health System in Detroit. This is back in 1999 and it said:

> At our recent ambulatory pharmacy and therapeutics committee meeting, we reviewed the atypical antipsychotics and have chosen Risperidone for listing on the Henry Ford ambulatory care formulary. The decision was made after consideration of comparative efficacy, safety, and cost data for the atypical agents compared to each other in first generation intermediate to high-potency antipsychotics.

So this kind of activity has been and is occurring in other health entities across the Nation. Again, we are not talking about thera-

peutic interchange of any patient who is on Olanzapine. That is not what we are talking about. What we are talking about is VA mental health professionals coming to similar conclusions as I read into the record by other health entities.

So I think it is a responsible action by our mental health professionals and certainly one that our PBM group, the medical advisory panel and our VISN formulary leaders, support.

Chairman ROCKEFELLER. Thank you very much.

Dr. Herdman, when we are confronted with a need for which we don't have the money, we start talking cost containment, and cost containment is terrific in the sense that you can, as we did in 1993, volume bargain or leverage the cost of prescription drugs down. On the other hand, it is the old argument about managed care versus, let us say, fee-for-service in Medicare or managed care under any circumstances.

The argument, and I can remember in the Finance Committee, 8 to 10 years ago, health professionals coming in and saying, managed care is going to get you savings, all right, for about 2 years, but then it is going to stop and the cost of their doing business is going to approximately go up with the cost of other people's doing business, as indeed we have seen in the cost per capita cost increase of health care between the United States and Canada, even though they have a totally different and presumably less expensive system. The costs, at least up until recently, have risen at about the same level.

So what I want to get from you and anybody else who would care to comment on this, particularly for the older, sicker population among our veterans, is is there a point at which cost containment in its broadest sense—not just the first 2 years or the let us leverage volume, buy down the cost of prescription drugs stage—at which cost containment as a philosophy begins to wrongly intersect with the legitimate health care needs of a fragile population?

Dr. HERDMAN. Well, I guess the answer is sure. Sure, there is such a point. The managed care example that you gave, I think, is true enough. The easy savings were taken, that is, the discounts from various kinds of providers and so on.

When you implement a cost containment program, my experience with that goes back 30 years when I was in New York working for a Rockefeller, actually. We were doing work on the Medicaid program. When you implement a cost containment program, you are going to annoy people because they are not going to get what they want. And the trick is, I guess, to stay the course, first of all, and continue to annoy them and to continue to get the savings, but not to get to the point where, when you are not giving them what they want, you end up not giving them what they need, and that is very, very difficult.

What happened in managed care, I think—this is an off-the-cuff opinion—is that it became politically difficult to not give people what they wanted. I don't know. There was very little evidence—I am thinking of some other IOM reports—that they weren't getting what they needed, although, of course, you could cite examples of disasters, but those are all anecdotes, and always occur no matter what kind of a system you look at.

So the answer to your question is, clearly, yes. Now, if you want to talk about the VA's national formulary and its drug benefit, the IOM, although it clearly pointed out some problems, as did GAO, and clearly thinks that there can be improvements, found by and large, that the system was based on good medicine and good science and was reasonably careful. Sure, they had problems with therapeutic interchange, and I think they are going to continue to have problems with therapeutic interchange. There is always that possibility, but by and large, the drug reviews were good, the therapeutic guidelines were good, and the system actually demonstrably did save money and so it allowed the VA to put the money elsewhere and, hopefully, deliver valuable services to veterans.

We couldn't find, and here I emphasize over and over again the caveat that the data available to look at the quality issue are lousy or not there at all, but we couldn't find any evidence that there was an impact on the quality of care of veterans not getting what they actually needed.

We did, I think you may recall—I don't know if I put it in my written testimony—that we did look, or actually the Harvard Department of Health Care Policy, which did the subcontract on costs, did look at the effect on inpatient hospital discharges for ulcer-related and heart-related conditions in the VA over the period before and after changes were made in the formulary to restrict closed classes of the proton pump inhibitors and the ACE inhibitors and various drugs which are used for heart conditions and for ulcer-related conditions and could not find any changes. I don't want to emphasize that particularly except to say that it just has to stand on its merits, which are not very great because it is a very crude study. But at least we tried to look.

When we looked—and this is a long answer, I am sorry to keep going on—when we finally got through with all that, we said those kinds of studies are very important to get at the issue you are talking about, and what we need, we suggested—recommended that the VA begin to collect information, cost information, expenditure information, utilization information, and outcome information which would help them and you decide whether they weren't getting what they needed, as opposed to what they wanted.

Chairman ROCKEFELLER. Comments?

Ms. BASCETTA. Yes. Back to our analysis of the non-formulary process, which, as we pointed out, was the one that we were the most concerned about, there were a couple other questions that we asked physicians in our survey. I will remind you it was a survey of 2,000 physicians, so it is statistically valid and projectible to the universe of VA doctors.

Only 63 of the 2,000 in the narrative portion of the survey told us about specific problems they had when they weren't able to get a non-formulary drug with a patient.

Chairman ROCKEFELLER. When they weren't able to do what?

Ms. BASCETTA. When they weren't able to get a non-formulary drug.

Chairman ROCKEFELLER. OK.

Ms. BASCETTA. Sixty-three patients is a lot if you are 1 of the 63 patients. But we took some comfort in knowing that we didn't have physicians running to us, telling us about all kinds of serious ad-

verse events or adverse health outcomes. But they did note suboptimal control of symptoms, particularly with asthma, pain, and GI disturbances and lipid control. So they are not insignificant.

They also told us that—33 percent of them told us that they didn't request a non-formulary waiver because they thought it would take too long, and 16 percent said that they didn't request a non-formulary waiver because they thought they would be denied. So to the extent that, in some locations, that process might have been a deterrent, we don't know. We don't have good information about what would have happened to the patient.

I would also like to point out that one of the most frequent responses that we got from the physicians was that the patient went and got the non-formulary drug, if they couldn't get it from the VA, outside. That is, they paid for it out of their own pockets. We didn't ask this question. I wish we have the foresight to think about the priority sevens when we were doing the survey. But it makes me wonder if some of those veterans had come to VA solely for that benefit, and when they weren't able to get the specific drug that their private physician had recommended, they went back outside. That is a very interesting question, I think.

Chairman ROCKEFELLER. Thank you. Did you want to add something?

Dr. MILLER. I did, Senator, just quickly. I think the effects on quality from cost containment have to be looked at systemwide. I want to underline Dr. Herdman's statement about the need for data to actually determine what is going on. Examples you can look at are the British health care system, where experts agree they have underfunded their public system and they use the safety valve of their private system to keep things going. In Canada, there is underfunding in certain areas, with the United States acting as their safety valve for people coming over here to get some specialized cancer treatments and things like that. So I think you have got to look comprehensively at what is going on in the system.

One example of how this interplay can happen between access and cost containment and how people get what they pay for, more or less, is what we do in our country for substance abuse, which, I think, is a big issue for the veterans' population. Those patients, the low-income veterans, don't have that "safety valve" that some patients have who can go elsewhere for their prescriptions. They can't afford to get it outside the VA. There is no "safety valve" for low-income veterans.

Chairman ROCKEFELLER. I want to thank all of you. I find these hearings very useful. It may not be so with all, who think there are too many questions or too detailed questions, but I think this is the way you ultimately learn issues, and very important issues affecting very important people.

I have taken a lot of your time and I appreciate that and thank you very much. This hearing is in recess.

[Whereupon, at 4:37 p.m., the committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF MOE ARMSTRONG ON BEHALF OF THE NATIONAL ALLIANCE FOR THE MENTALLY ILL

Chairman Rockefeller, and members of the Committee, I am Moe Armstrong of Cambridge, MA. I am pleased today to offer the views of the NAMI-National Alliance for the Mentally Ill on prescription drug issues in the Department of Veterans Affairs. I would like to direct my testimony to the important issue of prescription drugs for the treatment of severe mental illness.

In addition to serving on the NAMI Board, I am a veteran myself. I served in Vietnam in 1966. I was decorated for bravery in combat with a Navy Commendation Medal with a Combat V. My life was to be a career soldier until I became mentally ill.

Since the war, I have received mental health care and vocational rehabilitation services from the Veterans Administration. I went back to college and earned two masters degrees. I have worked in public mental health for almost fifteen years and have received many awards and acknowledgement from my service with the Massachusetts public mental health system. I also assist the Veterans Administration in setting up peer support groups in the North East region.

My prescription benefit comes through the mental health care and primary medical care, which I still get from the Veterans Administration. Veteran's mental health and physical health issues are very severe due to the nature of serving in both combat and the service. I have sometimes thought that my one-year in Vietnam was like ten years in a job outside the service. Veterans need specialized and intensive care. We also deserve care equal to care outside the VA. Part of that care is receiving access to the best medication available.

Having a major mental illness since the war means that I need good medication so that I can cool out. Once stable, I can do almost anything. I can go to school, go to work, and live in the community without excessive hospitalizations. Modern medications are almost a miracle. These new psychiatric medications are the best. They take away many of the psychiatric symptoms without downing out the person.

I take this medication. This is the best that I have felt since the war. I want everyone to have access to this new medication and I want people to continue to have access to the new medications. If your life were in danger of falling apart from mental illness or a member of you family were in the situation of psychiatrically falling apart, I am sure that you also would want access to this new medication.

I also currently serve as a member of the VA's Consumer Advisory Council on veterans with severe mental illness.

WHO IS NAMI?

NAMI is the nation's largest national organization, 220,000 members representing persons with serious brain disorders and their families. Through our 1,200 chapters and affiliates in all 50 states, we support education, outreach, advocacy and research on behalf of persons with serious brain disorders such as schizophrenia, manic depressive illness, major depression, severe anxiety disorders and major mental illnesses affecting children.

Mr. Chairman, for too long severe mental illness has been shrouded in stigma and discrimination. These illnesses have been misunderstood, feared, hidden, and often ignored by science. Only in the last decade have we seen the first real hope for people with these brain disorders through pioneering research that has uncovered both biological underpinnings for these brain disorders and treatments that work.

Today, I would like to urge the Committee to continue to monitor progress on implementation of restrictive drug formularies by VISNs that cover psychotropic medications. NAMI's Veterans Committee continues to hear reports of veterans with mental illness not getting access to the newest and most effective atypical anti-psychotic medications. Specifically, NAMI strongly objects to any treatment directive

that would interfere with the clinician's choice of the best medication for each patient based on that individual patient's clinical needs. While cost is an appropriate consideration, it should be only one factor in medication choice and must not be allowed to be the primary consideration in choosing a medication to treat severe mental illness. The VA's Committee on Severely and Chronically Mentally Ill veterans reports that currently 17% of VA's total pharmacy budget is spent on psychotropic medications, however there is great variance in the use of the newest and most effective medications which have been proven effective in treating schizophrenia. NAMI feels strongly that veterans with mental illness deserve full access to the newest and most effective medications.

NAMI would like to thank you and the members of this Committee who have questioned the VA on the development of treatment guidelines for schizophrenia. The VA has heard from both members in the Senate and the House regarding veterans having access to the newest and best treatments for their illness. Secretary Principi responded to these concerns and NAMI was reassured to see the following statements in his response letter and accompanying fact sheet of July 10, sent to several concerned members of Congress:

- ". . . I can assure you that the recommendations under development will continue to place clinician assessment of patient needs as the first consideration in the prescription of antipsychotic medication."
- "The proposed guideline and existing VISN guidelines assume the selection of atypical antipsychotic therapy must and will be based on physicians' assessment of clinical circumstances and patient needs."
- ". . . no patients who are currently being effectively treated with an atypical antipsychotic will have their medications changed as a result of the proposed guidelines."
- ". . . the proposed guidelines do not restrict a treating physician from prescribing any specific atypical antipsychotic that may best meet a patient's needs, based on the physician's clinical assessment."
- "Atypical antipsychotic prescribing will continue to be driven by clinical needs of patients as determined by their treating psychiatrist."

Mr. Chairman, unfortunately, actual events have not been reassuring. Although in theory the central role of clinical judgment is recognized in the draft guidelines, in practice there is ample evidence that the VA's schizophrenia guidelines are focused on cost-cutting rather than optimal clinical care. As NAMI feared, some parts of the Veterans Administration are implementing pharmacy guidelines in a way that is inconsistent with the letter sent by the Secretary, inconsistent with the draft guidelines, and most importantly, inconsistent with good evidence-based clinical care for our Nation's veterans. Policies are being implemented that do not serve the best interests of our Nation's veterans.

Cost containment of the atypical antipsychotic drugs appears to have become an overriding goal of some VA behavioral health programs, even though the cost of antipsychotic medications are overall less than 15% of the cost of treating the illness in most health care settings. NAMI's Veterans Committee members and staff have received reports that cost-control efforts have resulted in the following unacceptable events:

- Patients stabilized on the more costly atypical during an inpatient stay have been switched to a less expensive product soon after discharge, in direct contrast to VA assurances.
- Physicians' prescribing of the more costly atypical has been actively discouraged, both formally and informally. Pharmacists have called physicians to ask that they change their prescriptions to a less costly drug to comply with the "guidelines."
- Specific plans have been outlined to monitor physician practices, to assure that the more costly medication is prescribed less often, and to punish those who continue to prescribe the medication, believing it represents the best alternative for their particular patients.

Unfortunately, many of these instances have been documented informally, in part because VA staff report some concern about possible reprisals if they are publicly associated with these disclosures. Fortunately for our advocacy cause, one of the VA service chiefs was indiscrete enough to put his enforcement plan into writing.

This type of enforcement of "compliance with guidelines" is common but is usually more subtle and informal—and thus more difficult to document. Mr. Chairman, I believe you will agree that this program of forcing compliance through quantitative goals included in a physician's performance review is chilling. This sort of single-minded attention to cost-savings without regard for the clinical well-being of the individual veteran is exactly the kind of "guideline implementation" we have seen in the past and feared would accompany these new VA "guidelines." Our fears appear to be well-founded.

NAMI endorses basing treatment on the available scientific evidence and on the needs of the individual veteran. Research, and guidelines based on this research, call for most patients with schizophrenia to receive atypical antipsychotics. Although there is little evidence of overall group differences in effects on psychotic symptoms, there is ample evidence that these atypical antipsychotic agents differ from one another in biological effects and in side effects. There is ample clinical experience to suggest that individual patients may respond to one atypical medication but not another. Thus, clinical judgement plays a vital role in the selection of the most appropriate medication for a particular individual.

However, the fundamental purpose of the proposed VA guidelines is not guidance in selecting the best medication for a particular veteran—rather, the fundamental purpose is to reduce pharmacy costs by producing a shift to prescribing less costly atypical antipsychotic drugs. Such a shift in prescribing could be justified if the atypical antipsychotics were in fact equivalent and interchangeable. As noted above, they are not.

The VA states that "there is no valid medical evidence of the value of one drug over another in managing a disorder." In fact, there is ample evidence of substantial side effect differences among the medications, a vital consideration in the management of schizophrenia and in promoting adherence to treatment.

Mr. Chairman, the VA also states that "a number of private and public health care organizations are, in fact, using prioritization systems for the atypical antipsychotic medications similar to those proposed by VA." It is possible that some HMOs and some isolated programs may do so, but we would be interested to know which states and which major health insurance programs do this. In the public sector, we are not aware of any state that has implemented the type of restrictive guidelines that VA is proposing. Florida, Oregon, Kentucky, Hawaii, Missouri, Tennessee and Arizona have implemented preferred drug lists but exempt mental health drugs. Texas has implemented the Texas Medication Algorithm Project (TMAP) which supports open access to all atypical antipsychotic medications that are effective for treatment of a specific disorder. Within the algorithm, TMAP does not favor one specific medication over another. It is clinical judgement and patient preference and acceptance that determine the choice. The state of Texas follows TMAP and uses medication cost as a basis for choice only if there is no clinical reason to prefer one drug over another.

In most private healthcare plans, tiered co-pays are commonly used rather than restricting access to atypical medications. We know of no private plan that has implemented a restrictive policy that requires a patient to utilize the type of "step therapy" that VA is proposing for the use of atypical antipsychotics, and would be interested in any that could be identified.

In any case, the existence of isolated instances does not justify a wide-ranging VA policy. Within the past two years, isolated Medicaid and VA programs have proposed putting patients back on conventional antipsychotics, complete with a markedly increased risk of tardive dyskinesia. I believe we would all agree that these proposals were irresponsible and possibly unethical. The fact that someone interested in cutting costs will propose a plan does not make it right.

NAMI understands the VA's concerns about the pricing of pharmaceuticals and the VA's desire to pressure the manufacturer of the more costly antipsychotic to lower the price. But we find it utterly unacceptable for the VA to drag our Nation's veterans with severe mental illnesses into the middle of contractual issues and to use the veterans as leverage to lower acquisition costs.

NAMI believes that these guidelines should be suspended until there are better data to examine the complex issues of comparative efficacy, effectiveness, cost-effectiveness, and side effects. NAMI strongly urges this Committee to suspend this VA policy as applied to antipsychotic medications and to stop the promulgation of any new schizophrenia treatment guidelines until the National Institute of Mental Health presents the results of the Clinical Anti-Psychotic Trials of Intervention Effectiveness Project, which will look at the atypical antipsychotic medications and the advantages of one medication over another. At the very least, they should be suspended until the VA develops adequate controls over the implementation of guidelines to assure that clinician judgment regarding choice of medications is respected in practice as well as in theory. In particular, it is evident there would need to be, at a minimum:

- a directive forbidding the collection and use of individual physician prescribing profiles
- a directive forbidding the introduction of cost-containment criteria into performance reviews

• a formal monitoring program to examine all instances in which a less expensive medication is substituted for a more expensive medication to assure that stable patients are not switched

• a formal program by which violations of these directives by overzealous pharmacy or behavioral science managers could be reported without fear of reprisal

These constraints will help assure that treatment decisions are made by the veteran and the clinician, with the individual veteran's interests being the first and foremost concern.

We know we share a commitment to providing our veterans with the best available treatment for their illnesses and look forward to continued discussions about the best ways to assure optimal, effective, and cost-effective care.

Mr. Chairman, on behalf of NAMI 220,000 members, 1,200 affiliates, and the members of the NAMI Veterans Committee, I would like to thank you for the opportunity to share our views on prescription drug issues in the Department of Veterans Affairs.

PREPARED STATEMENT OF JACQUELINE GARRICK, ACSW, CSW, CTS, DEPUTY DIRECTOR, HEALTH CARE, NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION, THE AMERICAN LEGION

Mr. Chairman and Members of the Committee:

The American Legion appreciates the opportunity to provide its insights and experiences in dealing with the VA formulary and the prescription drug benefit provided.

The scientific advances in medicine have been miraculous! People are living healthier and longer lives due to the availability of technology and science. Screening and testing allows physicians to identify illnesses and diseases in their early stages and treatment protocols are becoming more sophisticated and targeted. Disease, pain, complications, side effects, and death are being mitigated. Medication continues to play a vital role in these advancements. The availability of pharmaceutical products, however, has become a major focus of debate. Issues range from ethical considerations, cost, demand, and availability. VA has not been immune, especially about its formulary and prescribing practices.

Last year, the Institute of Medicine (IOM) released a study, Description and Analysis of the VA National Formulary, to capture the challenges VA, the single largest purchaser of pharmaceuticals in America, faces as it attempts to optimize its approach in providing quality care to veterans. The American Legion applauds the breadth and depth of this analysis and shares concerns over restrictiveness, therapeutic interchange and generic substitutions, physician satisfaction and patient compliance.

The American Legion clearly understands the need for a formulary. Formularies offer pharmacological evidence-based treatment guidelines in conjunction with the ability to negotiate price using its leverage to drive market share. Formularies are commonplace in today's healthcare market. Managed care organizations, private hospitals and state Medicaid programs all rely on them. There is documentation that VA has relied on a formulary process since 1955. However, with the advent of the Veterans Integrated Service Networks (VISNs) and the Veterans Equitable Resource Allocation (VERA) methodology, the issue of pharmaceutical management has received heightened attention.

Veterans are very concerned about their access to pharmaceuticals and the quality of life they know they can attain through medication management. The IOM stated that only 0.4 percent of veterans complained about access to medication (based on data from patient advocates and the Veterans of Foreign Wars.) However, in a recent American Legion VA Local User Evaluation (VALUE) survey, it found that veterans were concerned about pharmaceutical access 88 percent of the time.

The greatest impact on the VA formulary system has been the fixed budget appropriation from Congress. It has forced VA to become more cost efficient and make more budget-driven decisions across the board. In its attempt to reduce duplication, streamline operations and cut costs, The American Legion believes that, in some areas, VA has gone too far. VA had estimated its FY 2000 pharmaceutical budget to be 15 percent. However, only 12 percent was spent nationally, with some VISN's significantly less than that (about nine percent).

Pharmaceutical purchasing and Hepatitis C Virus are the only two areas in which VA under spent from its projected budget. In spite of the fact that pharmaceutical prices are rising and research is costly, VA spent less money on treating veterans with medication than it could have done. The American Legion attributes this to the restrictive nature of the formulary and the complicated procedure to use non-formulary medications.

Although IOM's report concluded "The VA National Formulary is not overly restrictive." (IOM, 2000) The report did make several recommendations for changes, which included increased monitoring of generic substitutions and therapeutic interchanges, improve timeliness in adding newly approved FDA drugs to the formulary, improve non-formulary processes, provide education on formulary practices to veterans, and to continue the formulary based on quality practices and cost efficiency. The American Legion supports these recommendations, however believes IOM did not fully consider some of the problems associated with the formulary, and several other problem areas were not discussed in this report.

First, The American Legion notes that not enough attention was given to the off formulary process. During its site visits to VA facilities, physicians who report on the punitive nature and fear of poor performance evaluations they will get if they go off formulary too often confront The American Legion. Contrary to the position of VA Central Office, physicians do not feel free to use their best judgment in prescribing medication for their patients. The American Legion hears this complaint from providers all across the VA system and believes it is an unintended consequence of the non-formulary process. In addition, physicians describe this process as complicated and time consuming, which acts as a disincentive to do it.

In recent months, The American Legion has been involved with a serious discussion over an algorithm from VISN 22 (Law, Magcale 2001) that calls for patients to "fail first' with a "documented adverse event" on an anti-psychotic medication before the next drug in that class can be used. The American Legion strongly holds that physicians must be able to prescribe medication that is in the best interest of their patients without the fear of poor performance evaluations and disciplinary actions. Doctors, in a working relationship with their patients are the best and most cost efficient treatment asset the VA has. Properly trained and well supported, physicians and other providers make decisions in the best interest of the patient and should not be second-guessed by administrators and financial officers. "Getting it right the first time" is truly the best approach to medicine. Restrictions that require patients to fail are immoral and inhumane. The American Legion recognizes that these pharmaceuticals can be expensive, but are not nearly as expensive as prolonged inpatient stays, incarceration, or rehabilitation can be. The American Legion is aware that the House VA, HUD and Independent Agencies appropriations bill for FY 2002 calls for VA to "immediately suspend the fail first policy as applied to anti-psychotic medications" and is grateful to the committee for its intervention. The American Legion hopes that this directive will be applied to all drug classes and not just to the anti-psychotics.

The American Legion is also concerned about VA's use of generic substitutions and therapeutic interchanges. Although IOM does conclude that these practices are acceptable, it does note that "pharmaceutical equivalents may not always have the same therapeutic effect or safety profile." Other factors, such as compounding technology, bioavailability, and patient acceptance or compliance, may be important." (IOM 2000) Although the generic drugs are more economical, they are not as widely available as the brand name drugs (only about half of the brand name drugs have a generic version).

The greater concern, here, however is that the substitutes, as IOM points out, may not be as effective or safe. Medication that does not work costs more in the long run and results in additional clinic visits, testing, and hospitalization, not to mention the pain and suffering the veteran experiences. The American Legion strongly recommends that the efficacy and safety profiles of these drugs be a higher weighted criterion for selection than simple up front cost. The ultimate cost of ineffectiveness and adverse events are too high a price for the veteran to pay.

The American Legion views therapeutic interchanges in the same light as generic substitutions. Veterans should not be subject to changes in their prescriptions each year when VA renegotiates contracts with the pharmaceutical companies. Patients, whose condition has become stabilized, should not be forced to change medication it in order for VA to save money. This can result in non-compliance or compliance confusion, adverse events, and/or negative side effects for the veteran. For the most part, the VA patient has a more complex medical profile than does the patient enrolled in managed care in the private sector and can not be equally compared. Therapeutic interchanges do not contain the same, chemically identical, active ingredients and the American Medical Association (AMA) describes them as "not pharmaceutical equivalents." (AMA, 1997) This difference in a complex and frail patient who is already on multiple medications and receives various treatments increases the patient's risk for treatment failure.

A secondary issue to therapeutic interchanges is, how they are being made? IOM finds that "therapeutic interchanges usually means that a specific prescriber approval exists before dispensing except in settings where exchange according to a col-

laborative practice agreement or a preapproved policy and protocol is practical and has been accepted by prescribers." The American Legion has not found this to always be the case and that there can be confusion between the prescriber, the pharmacy and the patient. In focus groups conducted by The American Legion, a primary complaint from patients is that they get a prescription from their provider that they then take to the pharmacy, which will not fill the prescription because it is not on the formulary or they get a different drug. If they complain to the pharmacist, they are sent back to the clinic to discuss it with the prescriber, who by now, is seeing another patient. If they wait, the prescriber will change the prescription or contact the pharmacy on behalf of the patient and then will send the veteran back to the pharmacy. At any point in this frustrating scenario, the ailing veteran will feel too dejected and angered to continue and will depart the VA with no medication, returning when symptoms have worsened. The veteran is labeled as noncompliant and not seen as a candidate for newer treatment or research protocols.

IOM's report and VA leadership consistently recommends those issues surrounding patient's compliance and physician expertise is inherent in the education and training provided. The American Legion is a strong proponent of this concept and is in the process of launching its own patient and provider educational series, which is its Teamed for Health Campaign. This initiative will bring together the Department of Health and Human Services, (HHS) VA and industry to produce educational materials that The American Legion can distribute to its membership, VA users, and Medicare beneficiaries to improve the health status of those patients. Provider information will also be included in this initiative in order to keep physicians up to date on the latest research and treatment protocols. The American Legion sees this effort as a means of improving patient compliance and assisting in medication management, while improving best practice trends in VA and with HHS providers.

In another related matter, The American Legion has concerns over VA's Consolidated Mail Out Pharmacy (CMOP) system. Since 1999, CMOP service has been available nationwide to VHA's 22 VISNs. The program is currently running at maximum capacity with an estimated 61.3 million prescriptions annually. This production level has reached or exceeded the workload design of each of the CMOP facilities. Consequently, there are significant physical plant issues within the system. A prime example of this is the CMOP located at the Greater Los Angles Health Care System (GLAHCS). Established in a retrofitted warehouse on the grounds of the Brentwood Campus, annual production was originally designed at the level of 2.5 million prescriptions. In 2000, production was increased to 4.5 million prescriptions.

However, the building is poorly configured, limiting the capacity and efficiency of the operation. Additionally, the equipment frequently breakdowns, and the first-generation automated system (installed in 1994) is currently so old that parts are hard to get. The newest generation of dispensing equipment could nearly double the ratio of prescriptions dispensed to patients per worker. Clearly, new space and equipment are needed.

Overall, CMOP's program has no ability to respond to emergent need. Moreover, CMOP lacks the capacity to meet projected increases in workloads for FY 2002. There is no capacity for initiatives with other federal agencies beyond limited pilots. Solutions include:

- Expanding space and equipment at five CMOPs to new standard models.
- Replacing the two oldest CMOPs .
- Constructing additional CMOP facilities.

These are essential initiatives if CMOP's system hopes to be effective in its crucial role in the delivery of pharmaceutical services to America's veterans and their dependents.

In conclusion, The American Legion believes VA under spent on its pharmaceutical purchases as a result of a budget-driven philosophy that is clouding the intention of a formulary and is not always allowing for best practices to prevail. Restrictions, substitutions and interchanges need to be better monitored and carefully accounted for when utilized. Well-educated and well-supported providers are key to successful treatment and their clinical expertise and judgment should drive prescription practices for their patient population. Each veteran must be assured that they are getting the best possible care that not only the VA has to offer, but that the industry overall has available.

Mr. Chairman and Members of the Committee The American Legion is again grateful for this opportunity to present to you its experiences, and other comments in the intricacies of medication management within VA and concludes its statement.

PREPARED STATEMENT OF RICHARD W. HILLS, JR., PRESIDENT, VETERANS NETWORK FOR THE MENTALLY ILL

Mr. Chairman and Members of the Committee:

I am Dick Hills from Greenville, South Carolina. I am pleased today to offer the views of the Veterans Network for the Mentally Ill (VET NET) on the restrictions placed on select medications within the Department of Veterans Administration (VA) to the Senate Veterans' Affairs Committee.

I am a Vietnam Veteran who has come to view the devastating affects mental illness can have on both an individual and the individual's family, and the hope of recovery offered by the newer medications.

From a variety of vantage points, I have been part of the psychiatric community for the past 33 years. I have worked the wards as a psychiatric Aide at the Bangor State Hospital and in the front office as President and Chairman of the Board of Directors of Chestnut Hill Psychiatric Hospital in Travelers Rest, South Carolina.

This professional direction and advocacy activities are the result of personal life events. After four years in the Air Force, while attending graduate school on the G.I. Bill at Boston University, my first wife, in whose care I am still involved, was brutally raped and consequently suffered from sever chronic mental illness. As a result of this illness, she spent more than 20 year in a locked psychiatric hospital, a large part of that time in a psychotic state locked in a seclusion room. Today, after failing on medications for years, Clozaril, the first of the new atypical antipsychotic medications, has been instrumental in her recovery. She now lives in her own house with her pet dog and even has her own riding lawn mower. In addition to my first wife, I also am involved with my son who is currently treated with Risperdal.

As both a family member and as a professional, I have served on a variety of committees and boards over the years including Past Co-Chairman of the NAMI Veterans' Committee [currently the Veterans Network for the Mentally Ill], the Consumer Liaison Council of the Committee on Care of Severely Chronically Mentally Ill Veterans, The Task Force for the Revision of the Veterans Affairs Mental Health Manual, The (National Alliance for the Mentally Ill (NAMI) Finance Committee, Past Chairman of the Coalition of Networks and Councils of NAMI, South Carolina Department of Mental Health State Planning Council, Board of Directors NAMI of South Carolina, Board of Directors Greenville, South Carolina Alliance for the Mentally Ill to name a few.

GUIDELINES RESTRICTING THE USE OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

Guidelines that include fail first restrictions, or exclude newer agents such as Geodon, work to administer medications. The practice of medicine is both and art and a science.

Moreover, each veteran is an individual, and each individual reacts differently to each medication. For this reason, law requires that only properly licensed physicians prescribe medications for individual patients whom they have examined and whose symptoms they have considered.

Cover letters and/or other documents make it clear that the intent of these guidelines is to save money. It is well known and accepted that cost can most effectively be reduced by successful patient recovery. Psychiatric medication should only be used as one part of a comprehensive treatment plan. Ongoing evaluation and monitoring by a physician is essential. Psychiatrists receive extensive training beyond medical school to enable them to make these decisions. Such guidelines actively restrict access to important medications and may delay and/or hinder successful recovery and thus increase cost at the expense of the patient's well being.

The VET NET does encourage, however, guidelines or policy which would call for all mental health professionals employed by and who contract with the VA, to become familiar with, including ongoing training, the use of all atypical antipsychotic medications including Clozaril, Risperdal, Zyprexa, Seroquil, and Geodon.

ADDITIONAL RESTRICTING OF THE ATYPICAL CLOZARIL BY PROTOCOLS

A study recently published by the VA states, "Clozapine use deserves special scrutiny, as clozapine is the only antipsychotic agent proven effective in patients with refractory schizophrenia. In the VA, just 2.7% of veterans with schizophrenia received clozapine in FY00. This is surprisingly low rate of prescription, given that 20–25% of patients with schizophrenia are refractory to treatment with other agents."

With the VA serving close to 200,000 patients with psychosis, over 102,000 with a diagnosis of schizophrenia, it is estimated that in 2000 between 17,600 to as many

as 47,200 remained prisoners in their psychotic mind as a result of not receiving clozapine.

Considering that death from suicide among schizophrenic patients is 9% to 13%, the restrictive use of clozapine (which has a proven ability to reduce suicide and suicidal attempts), pose a real and measurable risk to life.

Low use of this agent is due to a VA wide protocol, which makes access difficult by requiring the submission of a multi page application for pre-approval before a patient may be started on the drug. The restricting effect of this protocol is compounded by the resulting lack of experience with the agent created by the restrictions and the stigma of danger that the special protocol implies. This protocol was appropriate when clozaril was the only atypical on the market and use of this new class of drug was unknown. Today, however, there are four other atypical agents available, and atypical use is common with approximately 70% of VA patients with schizophrenia receiving an atypical medication. Such a complex protocol is not required for any of the newer atypical agents and is unseen elsewhere in the country.

With this in mind, we recommend that barriers to the use of Clozaril be reviewed with the hope of eliminated or streamlining this protocol and improving access and utilization of this unique drug.

RESTRICTION OF PSYCIATRIC MEDICATIONS TO OLDER VETERANS

The VET NET encourages the committee to take the steps necessary to insure that veterans being treated in other areas of the VA such as nursing homes, residential beds, or on an outpatient basses be properly screened and when appropriate have access to the most effective medications under the supervision of a properly trained psychiatrist. Mentally ill geriatric patients are frequently overlooked simply as a result of age or frailty. We expect our seniors' to experience some effects of dementure as they become older, and do not think of this population as suffering from treatable biological mental illness. A report of the Surgeon General, however, shows that at least 10 to 20 percent of widows and widowers succumb to clinical depression in the year following their spouse's death. Moreover, it has been estimated that 75% of individuals being treated for Alzheimer's disease are not receiving any of the available medications for that illness.

In addition, the uncontrolled closure of beds has resulted in an acute shortage of psychiatric beds in many areas of the county. As a result, many mentally ill veterans who would otherwise be in an acute psychiatric bed are placed in nursing home or residential beds intended for older patients. A recent VA study showed that utilization of VA nursing home beds for psychiatric patients had increased from 3.1% in 1999 to 4.4% in 2000. This data not only confirms the presence of these patients, but also shows that this problem is expanding.

All of our veterans have earned and deserve access to the most effective medications available and to have them administer by properly trained individuals. We ask that psychiatric care is offered though-out the VA long-term care units under the supervision of individual's appropriately trained in psychiatry and who have unrestricted access to the newer, more effective medications.

This concludes my statement. Thank you for asking us to present views on this important issue and for your concern for our nations deserving mentally ill veterans.

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